

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION  
NATIONAL CENTER FOR HIV/AIDS, VIRAL HEPATITIS,  
STD AND TB PREVENTION  
DIVISION OF TUBERCULOSIS ELIMINATION**



**Meeting of the  
Advisory Council for the Elimination of Tuberculosis  
December 15-16, 2015**

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**Draft Record of the Proceedings**

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**US DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)  
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP)  
Division of Tuberculosis Elimination (DTBE)**

**Advisory Council for the Elimination of Tuberculosis  
December 15-16, 2015  
Atlanta, Georgia**

**DRAFT Minutes of the Meeting**

The US Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) Division of Tuberculosis Elimination (DTBE) convened a meeting of the Advisory Council for the Elimination of Tuberculosis (ACET) on December 15 and 16, 2015, in Building 8 of CDC's Corporate Square Campus, Conference Room A/B/C in Atlanta, Georgia.

ACET is chartered to provide advice to the Secretary of HHS and the Director of CDC regarding the elimination of tuberculosis (TB); to make recommendations regarding policies, strategy, objectives, and priorities; to address the development and application of new technologies; to provide guidance on CDC's TB Prevention Research Portfolio and program priorities; and to review the extent to which progress has been made toward eliminating TB.

Information for the public to attend the ACET meeting in person or via teleconference was published in the Federal Register in accordance with Federal Advisory Committee Act (FACA) regulations. All sessions of the meeting were open to the public.

**Call to Order and Welcome / Roll Call**

**Hazel Dean, ScD, MPH**

Deputy Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention  
Centers for Disease Control and Prevention  
ACET Designated Federal Officer (DFO)

Dr. Hazel Dean called the first day of the ACET meeting to order at 8:36 a.m. on Tuesday, December 15, 2015. She reminded the meeting attendees that ACET meetings are open to the public and that all comments made during the proceedings are a matter of public record. Members should be mindful of potential conflicts of interest identified by the CDC Committee Management Office (CMO) and recuse themselves from voting or participating in those discussions.

Dr. Dean conducted a roll call of ACET voting members, *ex officio* members, and liaison representatives present in the room or attending via teleconference. A complete list of meeting attendees is appended to this document as Attachment 1.

CONFLICT OF INTEREST DISCLOSURES	
ACET Voting Member (Institution/Organization)	Potential Conflict of Interest
Ana M. Alvarez, MD, FAAP (University of Florida College of Medicine)	No conflicts disclosed
Lisa Y. Armitage, MD, PhD (Heartland National Tuberculosis Center)	No conflicts disclosed
Jennifer Cochran, MPH (Massachusetts Department of Public Health)	No conflicts disclosed
Barbara Cole, RN, MSN, PHN (Riverside Co. Department of Public Health)	No conflicts disclosed
C. Robert Horsburgh, Jr, MD, MUS (Boston University School of Public Health)	No conflicts disclosed
Eric R. Houpt, MD (University of Virginia)	No conflicts disclosed
Michael Lauzardo, MD, MSc (University of Florida College of Medicine)	No conflicts disclosed
Jeffrey R. Starke, MD (Baylor College of Medicine)	Dr. Starke is on the Data Safety Monitoring Board for Otsuka Pharmaceuticals for pediatric trials of Delamanid.
James Sunstrum, MD (Wayne County, Michigan, TB Clinic)	No conflicts disclosed
David M. Warshauer, PhD, ABMM (Wisconsin State Laboratory of Hygiene)	No conflicts disclosed

Dr. Dean confirmed a quorum of ACET voting and *ex officio* members. She announced the following changes to ACET's membership:

- Dr. Jeffrey Starke is a new ACET member, replacing Dr. Susan Dorman.
- Dr. Karen Elkins is a new ACET *ex officio* member, representing the US Food and Drug Administration (FDA), replacing Dr. Sheldon Morris.
- Dr. Anthony Campbell is a new ACET *ex officio* member, representing the Substance Abuse and Mental Health Services Administration (SAMHSA), replacing Dr. Chana Rabiner.
- Ms. Susan Rappaport is a new ACET liaison representative with the American Lung Association.
- Dr. Robert Belknap is a new ACET liaison representative with the National TB Controllers Association (NCTA), replacing Dr. John Bernardo.
- Dr. Michael Bartholomew is an alternate ACET *ex officio* member from the Indian Health Service (IHS), representing Dr. Susan Karol.

- Dr. Susan Robilotto is an alternate ACET *ex officio* member representing Dr. Rupali Doshi from the Health Resources and Services Administration (HRSA).
- Dr. James Mancuso is an alternate ACET *ex officio* member from the US Department of Defense (DoD), representing Dr. Naomi Aronson.
- Dr. Fatima Munoz Carvajal is representing Dr. Gudelia Rangel as an ACET *ex officio* member the US-México Border Health Commission.
- Dr. William Baine, ACET *ex officio* member from the Agency for Healthcare Research and Quality (AHRQ), will retire from the agency on December 30, 2015.

**Barbara Cole, RN, MSN, PHN**

TB Controller

Riverside County (California) Department of Public Health

ACET Chair

Ms. Barbara Cole welcomed the participants present in person and via teleconference. She noted that the exciting meeting agenda would address many actions that have resulted from issues raised during previous ACET meetings. She reminded ACET voting and *ex officio* members to be present for roll calls throughout the meeting.

**CDC Updates**



**Jonathan Mermin, MD, MPH**

Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

Dr. Jonathan Mermin updated ACET on activities within NCHHSTP and its divisions. The center has had the following staffing changes:

- Dr. Eva Margolies, Associate Director for Planning and Policy Coordination, is retiring.
- Rich Wolitski, Associate Director for Performance Improvement, is going on a long-term detail to HHS as the Director of the Office of HIV/AIDS and Infectious Disease Policy.
- Michele Owen has been named the new Associate Director for Laboratory Science (ADLS).

An outbreak of HIV and hepatitis C recently occurred in a rural community in Indiana. Genetic analysis determined that all 184 infections occurred in prior six months. There was a quick response and the epidemic was controlled rapidly. The response included the Indiana State Department of Health as well as Indiana University, and CDC, including Epidemic Intelligence Service (EIS) officers as well as other public health officials from throughout the country. A service program with a “one-stop shop” approach was established. The approach seems to be working, as only three additional infections have been detected in follow-up testing. This outbreak could be perceived as a bellwether for potential risk in the future as the national epidemic of prescription opioid abuse, combined with heroin and other drug abuse, escalates.

The NCHHSTP Atlas has been updated with 2013 data for HIV, STDs, and TB. The atlas also includes county-level data and origin of birth for TB. A new advanced query will generate custom tables for multiple states or counties, years, and subpopulations. It is also possible to download the natural data for conducting statistical analyses. The atlas can be found at: [www.cdc.gov/nchhstp/atlas](http://www.cdc.gov/nchhstp/atlas).

NCHHSTP awarded a contract to Monitor Deloitte to improve the efficiency, outcomes, and impact of the center's programs by assessing current uses of data. NCHHSTP will also include clear performance measures and targets in all new Funding Opportunity Announcements (FOAs). The National TB Indicators 2013 State Comparison shows process and outcome measures associated with TB program performance. The overall national TB incidence rate is 3 cases per 100,000 population. Forty-one states have rates at or below that average, and nine states and the District of Columbia (DC) were above the national average. A number of states have higher rates than others. There are various reasons for these differences, and the state comparison helps NCHHSTP focus services on where they will be the most effective.

The NCHHSTP Epidemiologic and Economic Modeling Agreement (NEEMA), a five-year cooperative agreement, was initiated in fiscal year (FY) 2015. The agreement is intended to help all of the center's divisions model the cost-effectiveness of interventions or other aspects of their work as well as to understand the most cost-effective ways to address issues in order to most efficiently maximize the effects of their investments. NEEMA has three grantees: Emory University and Johns Hopkins University; Harvard University; and the University of California, San Francisco.

Some standard indicators have already been developed, and indicators will be developed for each of the divisions. For example, DTBE has an analysis of how many infections have been prevented because of its work and how much money has been saved as a result, as well as what would happen if there were interventions with certain populations, such as the foreign-born. This work represents an expansion beyond active case identification and treatment. Indicators and frameworks developed by other divisions can be applied to TB and other infections within the center.

Three NEEMA TB projects were initiated in FY 2015:

- Identifying and Recruiting Hard-to-Reach Immigrant Populations
- Cost-Effectiveness of Targeted TB/latent TB infection (LTBI) Testing and LTBI Treatment in High-Risk US-Based Populations
- TB Transmission Modeling

In FY 2016, the first-year TB-related NEEMA projects will continue, with the addition of the population groups of the homeless and intravenous drug users (IDUs) to the "Hard to Reach" Identification and Recruitment Project. TB Transmission modeling will take place in the four key states of California, Texas, New York, and Florida. New international projects and crosscutting projects will be initiated in FY 2016.

NCHHSTP is expanding its use of Advanced Molecular Detection (AMD) through software and in the laboratory. The DTBE Laboratory Branch has been awarded funding by CDC's Office of Infectious Disease (OID) for a project on building capacity for surveillance using Whole Genome Sequencing (WGS). The goals of the project include implementing genomic surveillance at the



national level and building WGS capacity at the state level. The concept incorporates connecting infections to each other to recognize clusters or outbreaks in relatively real time. Other NCHHSTP divisions are also considering how to use new technology to build core aspects of public health.

Dr. Mermin presented updates from NCHHSTP divisions:

#### DTBE

DTBE released a surveillance report on *Reported Tuberculosis in the United States, 2014*. It can be found at <http://www.cdc.gov/tb/statistics/reports/2014/default.htm>. The report notes the lowest active case rates ever reported of 9421 cases in 2014, but because TB efforts have been so successful, there is disappointment that the rates represent only a 1.5% decline from 2013. The percentages of persons with TB who were HIV-positive declined more substantially to 6% in 2014. This figure is a 7% decline since 2011 and 48% decline since 1993. These improvements are likely due to increased antiretroviral therapy (ART) availability as well as more rigorous screening and prophylaxis. An infographic of the data presented in the report is available at <http://www.cdc.gov/tb/publications/infographic/default.htm>. New statistics from the division indicate that up to 13 million people in the US have LTBI.

The 36th Semi-Annual Tuberculosis Trials Consortium (TBTC) Meeting was convened in Atlanta, Georgia from October 19-22, 2015. This group remains vibrant and is particularly active in cutting-edge work such as a TB treatment shortening trial in partnership with AIDS Clinical Trials Group (ACTG). DTBE also released a new online course on TB for clinicians: [http://www.cdc.gov/tb/webcourses/Course/main\\_menu/index.html](http://www.cdc.gov/tb/webcourses/Course/main_menu/index.html).

#### Division of HIV/AIDS Prevention (DHAP)

The recent National HIV Prevention Conference included important findings. Pre-exposure prophylaxis (PrEP) is becoming more common in the US, as its proven efficacy in studies is moving into operational experience in pilot programs in which it seems to work in many cases better than in the trials. This difference could be due to early adopters adhering better or to other factors. Additionally, more attention is being paid to shifting the cohort of HIV-diagnosed persons to achieve viral suppression through more attention to treatment access. Acting along each “pillar” along the continuum of care is difficult, but it is important to maintain linkages to care.

HIV data from 2005 – 2014 show the first sustained decreases in HIV diagnoses in the US for over 2 decades. The decreases are in almost all population groups, illustrating not only a decrease in the number of HIV infections, but also in relative disparities. Declines are particularly notable among African American women. The group with the highest HIV incidence and prevalence in the US is young African American men who have sex with men (MSM). This continues to be an area of major concern and programmatic opportunity, even though there has been a leveling off of diagnoses in recent years. The data allow DHAP to maximize interventions by focusing on the populations of most need.

Despite progress, disparities persist in HIV. Prevalence of HIV is still associated with a number of social determinants of health (SDOH), including poverty, education, unemployment, homelessness, and region of residence. The most cost-effective interventions and services must be delivered to disproportionately affected populations. The percent of undiagnosed HIV is highest in the southern part of the US, where there are significant disparities and persons with HIV are two to three times more likely to die than in other parts of the country. The disparity of region seems to be increasing.

### Division of Adolescent and School Health (DASH)

Every two years, DASH conducts a study of school health policies and practices. The 2014 data indicate that while there is some sex education in approximately three-quarters of all high schools in the US, there are limitations to, and variations among, the aspects of sexual education that are covered and whether sexual health services are available in safe and supportive environments for lesbian, gay, and bisexual (LGB) students in schools. The 11 key HIV, sexually-transmitted disease (STD), and pregnancy prevention topics are covered well in some regions, such as the northeast, but are limited in other regions.

DASH presented a successful Public Health Grand Rounds on Adolescence: Preparing for Lifelong Health and Wellness. The Webcast can viewed at: <http://www.cdc.gov/cdcgrandrounds/>. The website is mobile-friendly. The division also released a fact sheet on “Bullying and Absenteeism: Information for State and Local Education Agencies” in recognition of the need to focus on absenteeism. Of bullied students, 16% missed one or more days of school because of safety concerns in past 30 days. These issues particularly affect sexual minority youth.

### Division of Viral Hepatitis (DVH)

DVH is helping the Cherokee Nation with its first-ever viral hepatitis National Elimination Project: “Path towards Elimination of Hepatitis C Virus (HCV).” There are great public health opportunities to address viral hepatitis in the next decade. Treatments are now reduced to 8 to 12 weeks with high success rates, but the treatments are expensive, and other restrictions and obstacles must be addressed. The treatment effectiveness is well-proven, however, and there are increasing connections between the treatments and the people who need them. The Cherokee Nation has an extensive health system, and the political structure’s primary issue is health. HCV has a 6% prevalence in the Cherokee Nation, and it is encouraging that they have chosen to focus on it.

### Division of STD Prevention (DSTDP)

DTSDP released a surveillance report on STDs in the US. There had been encouraging decreases in Chlamydia, but based on the 2014 data, reported cases of chlamydia, gonorrhea, and syphilis increased for the first time since 2006. The case rate of chlamydia is up 3% since 2013. Rates of primary and secondary syphilis increased by 15%, and rates of gonorrhea increased by 5%. Rates are also particularly high among gay men and MSM with HIV infection, indicating a sexual network of transmission that must be addressed. The increases could be due partially to detection bias or could be real, but they are important to address because STDs are the top-reported diseases in the US. Young people represent 50% of the infections.

With the Public Health Accreditation Board (PHAB), the National Association of City and County Health Officials (NACCHO), and the National Coalition of STD Directors (NCSD), DSTDP hosted a Webinar on the Disease Intervention Specialists (DIS) Certification Project. The project is a comprehensive activity on creating standard training for DIS. Various certification model options and administration and management approaches are being considered. Currently, it is challenging to determine the credentials of a DIS. This project will address this challenge, with a broader perspective on partner services and contract tracing. The project will strengthen the organizational capacity of health departments to support DIS work in STDs and related infections, as well as other communicable diseases and emergency response.



ACET and Dr. Mermin discussed several aspects of his presentation.

- There is a significant controversy in the pediatrics field regarding whether to include foreign-born parents as a risk factor for testing children for TB. CDC internal or collaborative modelers could provide insight into this issue, which carries a number of epidemiological and economic implications.
- One of the important aspects of TB is that considerable success over the past 2 decades could go in the other direction as it has in other countries, if efforts are not sustained or expanded.
- The intersection of TB and HIV has served as a model for program collaboration and education. For instance, Asian-American populations are target populations for screening for both TB and hepatitis B. Because the patient population is large, primary care physicians could be important partners.
- Regarding efforts to target diabetics for improvements in screening for LTBI and for management as a high-risk group, Dr. Philip LoBue (Director, DTBE, NCHHSTP, CDC) noted that diabetics are a major population. Without an additional risk factor for TB, testing all diabetics could devote large resources for limited impact. The first step in targeting people at risk for TB infection may be to focus on high-risk populations who also have a risk of progression, such as foreign-born persons who have diabetes.
- The AMD initiative is of critical importance. It has focused largely on laboratory capacity and less on the analytic and information technology (IT) capacity needed for processing data. Many programs do not have epidemiologic capacity to conduct routine TB work. DTBE has focused specific resources on epidemiology and interpretation, and there will likely be a lag as the division resolves these questions before dissemination. Epidemiologic and interpretive capacity must be built as laboratory capacity is built. WGS has potentially significant implications. The technology allows for linkage at an individual level, where epidemiology in the past has focused on the group level. The entire AMD enterprise requires laboratory capacity, software for interpretation, and programmatic capacity to respond. Results of laboratory tests are not useful if they are not understood. Information cannot be interpreted accurately at the local level without knowledge and epidemiological expertise. Advice must be available for local programs.

### DTBE Director's Update

#### **Philip LoBue, MD**

Director, Division of Tuberculosis Elimination  
National Center for HIV/AIDS, STD, Viral Hepatitis and TB Prevention  
Centers for Disease Control and Prevention

Dr. LoBue offered ACET updates on:

- Strategic planning materials consolidation
- Drug Susceptibility Testing (DST) Reference Center
- Updated estimate of recent transmission of TB in the US
- National Health and Nutrition Examination Survey (NHANES) estimate of LTBI
- Status of United States Preventive Services Task Force (USPSTF) review of LTBI testing

- National Action Plan for Combating Multidrug-Resistant Tuberculosis (MDR-TB)

### Strategic Planning

The previous TB strategic planning website was a list of items related to TB activities and priorities. The list encompassed the framework and major ideas of TB in the US but needed to be consolidated and synthesized into a single plan, which is now presented on the DTBE website at <http://www.cdc.gov/tb/about/strategicplan.htm>. The main goal of the DTBE Strategic Plan is to reduce TB morbidity in the US, with a particular focus on reducing disparities. The strategies and goals, which also encompass ending neglect, are to:

- Maintain control of TB
- Accelerate the decline of TB
- Develop new tools for the diagnosis, treatment, and prevention of TB
- Increase US involvement in international TB control activities
- Mobilize and sustain support for TB elimination
- Track progress toward the goal of TB elimination and regularly report on progress

DTBE no longer has the lead in US involvement in international TB activities, but it is still an important area to the division because of high rates of TB in the US among foreign-born persons. The division collaborates with internal partners on international issues, which are important to eliminating TB in the US. The goals align with the NCHHSTP Strategic Plan, which has a target of reducing the TB case rate to 1.4 cases per 100,000 population by 2020.

### Drug Susceptibility Testing Reference Center

The DST Reference Center was established in collaboration with the Association of Public Health Laboratories (APHL), and the contract was awarded to the California Microbial Diseases Laboratory (MDL). The purpose of the DST Reference Center is to ensure quality first-line and second-line DST, particularly in public health laboratories with low test volumes of fewer than 50 per year. The center also ensures that the laboratories have access to molecular testing. As of September 2015, 13 public health laboratories have enrolled for full services, with an additional two low-volume laboratories enrolling for molecular and second-line testing services.

### Updated Estimate of Recent Transmission of TB in the US

A recently-published DTBE project estimates recent transmission versus reactivation of TB. This question is central to the strategic approach to TB elimination in the US. Previous estimates suggested that reactivation accounted for approximately 75% of TB cases, and recent transmission accounted for 25% of cases. This study used the National TB Genotyping and Surveillance Network (NTGSN) dataset, which is slightly older but which includes field investigation information, such as interviews, which is not routinely available in current systems for monitoring epidemiological trends. The approach used a novel method requiring identification of a plausible source case, based on geographical proximity as well as matching genotype. Field investigation results confirming contact and transmission among cases were the gold standard. The study suggests that the rates of recent transmission are lower than previously thought at 11.4%. The percentage of TB cases originating from reactivation of LTBI may be higher than previously thought at as high as 85% to 90%.

### NHANES Estimate of LTBI

Another project estimated LTBI prevalence in the US. It was conducted as part of the 2011-2012 NHANES and assessed the use of the Tuberculin Skin Test (TST) and Interferon-Gamma Release Assay (IGRA) QuantiFERON-TB (QFT) to consider the prevalence of LTBI. NHANES is conducted on a regular basis and assesses multiple aspects of the health of the US population. Estimates of prevalence were generated based on positive TST, positive IGRA, or both positive. The TST results could be compared to the 1999-2000 NHANES, but that survey did not include IGRAs. The results of the project offered imperfect answers. Prevalence is higher among foreign-born persons as reflected in the following tables:

US population LTBI prevalence estimate by positive test result [95% Confidence Interval (CI)]		
TST 1999-2000	4.3% [3.5-5.3]	10.7 million persons
TST 2011-2012	4.7% [3.4-6.3]	13.3 million persons
QFT 2011-2012	5.0% [4.2-5.8]	14.1 million persons
Both positive 2011-2012	2.1% [1.5-2.8]	5.9 million persons

Foreign-born US population		
TST 1999-2000	18.1% [13.5-23.8]	5.4 million persons
TST 2011-2012	20.5% [16.1-25.8]	8.1 million persons
QFT 2011-2012	15.9% [13.5-18.7]	6.3 million persons
Both positive 2011-2012	9.3% [7.4-11.7]	3.7 million persons

DTBE re-analyzed the 1999-2000 NHANES data to ensure that the methodologies used were the same in both data sets. The digit preference was different in the two surveys, so the analysis adjusted for the difference. In the 1999-2000 study, the digit preference was approximately 10 millimeters (mm). The preference in 2011-2012 was for 9 mm. In one case, the digit preference would lead to more positive tests, while the second digit preference would be more likely to yield negative test results.

The USPSTF is reviewing LTBI testing. The evidence review was completed in June 2015. The workgroup that presented all of the evidence and information has prepared preliminary recommendations for the full task force to consider. The release of the draft recommendations and evidence review to the public for comment is tentatively scheduled for early 2016.

The National Action Plan (NAP) for Combating MDR-TB is related to the larger action plan for combating antimicrobial resistance (AR). Elements of the AR plan pertain to TB, but TB deserves its own plan. The White House Office of Science and Technology Policy (OSTP) led the development of the NAP, which describes critical actions that should be taken by federal departments and agencies to combat the global rise of MDR-TB. The NAP is projected to be released in December 2015. Public meetings have been held about the plan, but the actual draft of the plan is yet to be released.

The MDR-TB NAP is divided into three goals:

- Goal 1: Strengthen Domestic Capacity to Combat MDR-TB
- Goal 2: Improve International Capacity and Collaboration to Combat MDR-TB
- Goal 3: Accelerate Basic and Applied Research and Development to Combat MDR-TB

The major activities for the domestic goal are to:

- Strengthen surveillance including capture of molecular DST and more detailed treatment information
- Strengthen state and local capacity for contact investigation and outbreak response related to drug-resistant cases
- Improve security of drug supply for TB treatment (i.e., no more shortages)
- Find better options to provide care for patients who do not have a medical home
- Improve ability to ensure completion of treatment for persons who travel outside of the US while on treatment (e.g., binational case management)

ACET discussed Dr. LoBue's presentation.

- ACET discussed a potential role for the National Institutes of Health (NIH), which recently took on some drug-resistant TB cases. NIH has a research protocol for MDR-TB patients. CDC is helping NIH work with TB controllers to identify patients who are good candidates for the protocol. This work may also be helpful to local programs that do not have sufficient resources to work with these patients. NIH can take only a few cases at a time and cannot accept routine MDR-TB cases. ACET might consider inviting a representative from NIH to describe the work.
- There are examples of discordance between GeneXpert® results and final results in low-prevalence settings. GeneXpert® is accurate, but there are problems with ascribing resistance. It would be useful to have a reporting mechanism to capture GeneXpert® results and match them with susceptibility testing. Molecular results should be captured for all patients, not just drug-resistant patients. The surveillance system for MDR will be able to detect patients who are initially diagnosed with MDR, but subsequently proven not to have MDR. It will be possible to calculate the extra expense associated with treating patients with misdiagnosed MDR.

### **Activities to Move the US Toward TB Elimination**



#### **Carla Winston, PhD, MA**

Associate Director for Science

Division of Tuberculosis Elimination

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

Dr. Winston updated ACET on the status of the DTBE Research Agenda, including the timeline, Research Oversight Committee, priorities, inventory, and next steps. Much of the groundwork for creating the agenda was conducted by a research workgroup in 2014. Dr. Winston began as the Associate Director for Science (ADS) in March 2015, and the Research Oversight Committee was convened in April 2015 to review the division's priorities and research. The committee was created at the recommendation of the research workgroup, which identified a need for an internal science oversight committee.

The Research Oversight Committee solicited proposals for funding for the end of the FY. Eleven proposals were submitted, primarily for operational research. Two proposals were funded:

- Workshop on TB and Homelessness
- Whole Genome Sequencing Cloud Storage

The internal research inventory was completed in the summer of 2015 with input from DTBE branches and staff. The Research Oversight Committee includes at least one member from each DTBE branch. The committee activities include:

- Assessing research priorities
- Compiling the research inventory
- Reviewing projects and new research proposals, including ongoing work within the branches or consortia
- Encouraging novel collaboration and understanding of research and programmatic needs

DTBE has four major categories of research priorities, which are to:

- Decrease incidence of TB infection
- Decrease morbidity and mortality from *M. tuberculosis*
- Decrease health disparities across groups affected by TB
- Conduct surveillance for adverse events and treatment outcomes

The research inventory was restricted to projects with greater than \$50,000 anticipated in FY 2016. The committee requested projected staff needs and effort through 2020. Some of the projects continue for the five years, and others are shorter-term. The committee also requested descriptions of cross-branch collaborations, such as in data management, evaluation, behavioral studies, or statistical support.

The research inventory includes:

- TB Epidemiologic Studies Consortium (TBESC)
- TB Trials Consortium
- Laboratory Research and Operational Projects
- NCHHSTP Epidemiologic and Economic Modeling Agreement (NEEMA), a Center-wide initiative

Major studies within TBESC are:

- Prospective comparison of TST and IGRAs in diagnosing TB infection
- Evaluating and implementing LTBI surveillance and evaluating the TB prevention cascade
- Reproducibility and repeatability of IGRAs in different testing conditions
- Diabetes among LTBI-screened persons

Active studies within TBTC include:

- Study 31 Phase III Rifapentine-containing Treatment Shortening Regimens
- Study 32 Phase II Multidrug-Resistant TB Fluoroquinolone Optimization
- Study 35 Phase II Pharmacokinetics and Tolerability of Rifapentine for LTBI in HIV-uninfected Children
- Study 36 Collect Clinical Data and Sputum Specimens for 12 Months Post-Treatment

The Laboratory Branch has a number of ongoing research projects, including the following:

- Molecular Assays for Drug Resistance Detection
- Mechanisms of Drug Resistance
- Immunology and Cell Biology of TB Infection and Vaccination
- Whole Genome Sequencing, including research aspects and operational aspects related to IT and management of data output
- Assays to Enhance Clinical Service for Drugs
- Evaluation of Clinical Decision Making
- Examination of Susceptibility Testing Methods, including first-line but focusing primarily on second-line DST methods in domestic public health laboratories
- Best Practices for Laboratories

While most international TB research and programs outside of TBESC and TBTC transitioned to the proposed Division of Global HIV and TB, DTBE retained the Botswana research profile in the DTBE Office of the Director. The Botswana site is anticipated to close in 2017, and the research activities, which include the following, are in close-out mode:

- Kopanyo Dynamics of TB Transmission in high-HIV prevalence areas
- Xpert Package Rollout Evaluation Study (XPRES) Evaluation to Assess Xpert
- RIFASHORT Phase III High Dose Rifampicin Trial
- XpertViral Load Evaluation Study
- Barriers to Multidrug-Resistant TB Care, including detection and effective treatment outcomes

The Field Services Branch (FSB) and other DTBE branches have several ongoing investigations and operational studies, including the following:

- Post-Marketing Surveillance for 3 Months Once-weekly Rifapentine+Isoniazid: this project has taken a number of forms, including data contributed from public health departments as well as new ideas for post-marketing surveillance in IHS and among homeless populations
- Bedaquiline Treatment Registry for MDR-TB patients
- Surveillance of TB among Immigrants to Hawaii, with a focus on B1 immigrants from the Philippines, who have experienced higher rates of TB within the first year after their arrival in Hawaii
- Predicting Outbreaks, based on historical information
- Growth of TB Genotype Clusters



- Surveillance for Drug Resistance Mutations and collecting enhanced surveillance results for phenotypic and molecular data regarding drug resistance in the national TB surveillance system

**Advice and input requested from ACET by DTBE:**

- ☐ Identify gaps, if any, in the research agenda
- ☐ Solicit proposals to address gaps if needed
- ☐ Determine the priority of new proposals in relation to existing research
- ☐ Based on prioritization, determine whether any new proposals should be funded and existing research should be discontinued

It is a priority to disseminate all research. In 2015, DTBE published over 70 articles. DTBE shares research findings within the scientific community; with policy makers for the National Action Plan; with TB controllers; with the general media and social media; and with APHL and public health laboratories regarding issues such as WGS.

ACET discussed the following topics pertaining to the DTBE research agenda:

- In the past, ACET has discussed overseas screening, B1 notifications, and the potential for interventions at the state and local levels post-arrival. There are significant gaps in the Electronic Disease Notification (EDN) process. These gaps could be evaluated or undergo a research review in order to determine the extent to which notifications for individuals arriving in the US are received at the state and local levels. DTBE works closely with CDC units that focus on these issues.
- Research capacity is being lost at the local level. Given the lack of local capacity for data analysis, there are limitations to what local programs can do regarding the preventability of TB with the Report of Verified Case of Tuberculosis (RVCT) and with other data. The research agenda does not address preventability of TB cases.
- The Clinical Research Branch of DTBE recently approached the Surveillance and Field Services Branches to develop a proposal seeking funding to involve concepts related to large trials.
- The goal to decrease disparities across groups affected between TB is admirable, but previous work suggests that the way to accomplish this goal is to decrease TB in all groups. Generally, reducing TB across the board may reduce disparities; however, a combination of specific, targeted approaches and general elimination strategies is needed.
- There was discussion regarding checking vitamin D levels in populations in outbreak situations. The vitamin D levels could have implications for resistance and susceptibility and could point toward protective strategies. TB surveillance data has limited findings related to vitamin D, and NHANES data indicate that most of the US population is vitamin D deficient.
- DTBE welcomes input from ACET regarding innovative ideas that are underrepresented in the division's research inventory and regarding ongoing initiatives that could be cut to fund new work. The division will set research priorities internally and welcomes ACET's input into the process.

With that, Ms. Cole dismissed the group for a break at 10:19 a.m. The meeting reconvened at 10:34 a.m. Dr. Dean conducted a roll call of ACET voting and *ex officio* members and liaison representatives present in person and via teleconference. A quorum was present.

## Overview of Biomedical Advanced Research and Development Authority (BARDA)

### **Applying Lessons Learned from the Medical Countermeasure Enterprise to Tuberculosis**

**Nicole Lurie, MD, MSPH**

Assistant Secretary for Preparedness and Response

US Department of Health and Human Services

Dr. Nicole Lurie thanked ACET for its work and presented an overview of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within HHS and of the Biomedical Advanced Research and Development Authority (BARDA).

ASPR is a relatively new office. It was formed as a “lesson learned” subsequent to Hurricane Katrina in 2005, when Congress decided that all of the US government components that focus on the public health and medical aspects of emergencies should be assembled in one place. BARDA was launched in late 2006.

ASPR has three major components:

- A policy office is responsible for policy coordination for various public health emergencies within HHS, among HHS and other federal agencies, and among HHS and state and local governments.
- A response component administers the Secretary’s Operations Center (SOC) and serves as a focal point for the International Health Regulations (IHR). It also oversees the National Disaster Medical System (NDMS), which dispatches teams to provide care in disasters, and a hospital preparedness program.
- BARDA is responsible for making countermeasures for various biothreats, and increasingly for emerging infectious diseases.

Dr. Lurie has been in her position since 2009 and has participated in responses to many types of events, such as natural weather events, infectious diseases, oil spills, and mass shootings. BARDA is guided by the National Health Security Strategy (NHSS), which focuses on building community resilience. Individuals and communities that are resilient fare better in disasters and recover faster from them. NHSS also recognizes global interconnectedness and understands, as Ebola and TB have illustrated, that the best way to protect the US and the US population is to prevent health threats from emerging and to control them at their source. ASPR is also guided by IHR, the Global Health Security Agenda (GHSA), and the National Strategy for Combatting Antibiotic-Resistant Bacteria (CARB).

The countermeasure enterprise encounters a number of challenges and barriers in common with the development and accessibility of countermeasures for TB, such as the development of diagnostics, vaccines, therapeutics, and other mechanisms of TB control. Since BARDA was chartered, its primary responsibility has been to focus on agents determined by the US Department of Homeland Security (DHS) to be material threats. These agents are largely infections that bioterrorists or other malicious actors could use on the public. BARDA has additional authority to focus on emerging infectious diseases, including pandemic influenza and Ebola.

BARDA's funding comes from two sources: 1) An appropriation called Project Bioshield, which funds countermeasures that are on the list of material threats determined by DHS. In order for these funds to be used for TB countermeasures, DHS would have to determine that TB represents a material threat to US security; and 2) Funds available for the advance development of medical countermeasures. These funds support agents that are material threats or are emerging infectious disease.

BARDA does not work in a vacuum. It is tied to the entire Public Health Emergency Medical Countermeasure Enterprise (PHEMCE). PHEMCE brings together all of the components of the US government to develop countermeasures and includes NIH, CDC, FDA, parts of DoD, the US Department of Agriculture (USDA), and DHS. PHEMCE works through a governance structure to decide where investments will occur and how projects move.

Much of the determinations regarding countermeasures come from DHS, but PHEMCE also considers emerging diseases and threats, such as Ebola, Middle East Respiratory Syndrome (MERS), and potentially Zika virus. Because countermeasure development is a lengthy process, PHEMCE begins the work as early as possible. A framework guides work in influenza.

The work begins with a consideration of the end users of the countermeasures in terms of what the public health community needs to combat an infectious disease. The community may need a diagnostic, vaccine, therapeutic, personal protective equipment (PPE), or other measure. The countermeasures must be usable as well as acceptable to the general public. The paradigm moves from basic research through clinical development and licensure so that measures can be distributed and administered. Each agency has a set of responsibilities within PHEMCE. Basic research typically occurs at NIH, though some occurs at CDC or in components of DoD. The research builds an understanding of the basic mechanism of disease. The pre-clinical development process progresses, and at a certain stage of development, BARDA conducts advanced development to the point of licensure for inclusion in the Strategic National Stockpile (SNS), vendor-managed inventory, or for broader use.

The H1N1 influenza pandemic was an example of implementation of countermeasures. A vaccine was created past the peak of the pandemic. As a result, PHEMCE redesigned elements of its process. The relationship with FDA was a large part of the redesign. Previously, a product is presented to FDA further in the development process. The company producing the product may be surprised by what FDA requires if there has not been discussion beforehand. Further, FDA may not have appropriate science to determine how to regulate new products. The process now incorporates FDA earlier in the development process. Developers work with government scientists in a more collaborative manner so that FDA can suggest studies that might be required for product licensure.

The product development process is long and cumbersome. By the time pre-clinical development is completed, many product candidates have dropped out of the pipeline. Early, promising products have a 1% to 3% probability of reaching licensure. BARDA has succeeded in including 12 non-influenza-related medical countermeasures in the SNS, with 12 more countermeasures anticipated by 2019.

Because the process of development is so long, BARDA is increasingly focused on making investments that have peace-time use. Dual-use products are desirable. PHEMCE and BARDA have entered the realm of AR because of this dual-use strategy. Novel antibiotics are needed for resistant anthrax or plague. At the same time, it could be possible to develop an antibiotic to treat

resistant gonorrhea, for instance, or other resistant organisms. The federal investment in dual-use products can be less because of the potential commercial market. Further, these products may not need to be stored in the SNS. They can be rotated through vendor-managed inventory.

For instance, dual-use products for radiation and nuclear events are used in cancer chemotherapy and are approved in the event of a nuclear catastrophe. Thermal burn products that are developed for a nuclear catastrophe can also be utilized for other kinds of burns, reducing the burden on the burn system. The products can also be helpful for diabetic ulcers.

The CARB initiative addresses AR bacteria. BARDA has limited funds for this work, and the funds are focused on the three organisms that CDC has deemed to be the most significant threats. With additional funds, it is conceivable to work on other resistant organisms.

Most of the developers of countermeasures for biological agents are not large companies, but small start-ups or academics. Many groups fail for business reasons, and others fail because of a lack of resources to complete the drug development process. BARDA has developed a set of core services to help companies in the process. For instance, BARDA can support companies as they work with FDA. BARDA has a non-clinical animal network that is available to drug developers that can assist with animal model development. Additionally, the Center for Innovation and Advanced Development in Manufacturing (CIADM) can assist companies in scaling up and piloting new products to test in clinical trials. After the H1N1 pandemic, it was clear that the bottleneck for vaccine access was not related to the vaccine itself, but was due to the rate at which the vaccine was distilled into vials and syringes. To address this problem, BARDA created a “Fill and Finish Network” that can be activated as necessary. The core services have been used quickly after H1N1, particularly the Animal Studies Network, the Fill and Finish Network, and the Clinical Studies Network, which supplements NIH and CDC, which were useful during the Ebola crisis.

A new BARDA initiative is in continuous manufacturing. The initiative began in 2015 in collaboration with the FDA. The process of drug and vaccine manufacturing takes place one step at a time, with the different steps frequently occurring in different buildings and different sites. At each step, there are opportunities for accidents and contamination. Each step requires inspection and re-inspection for quality. Time, energy, and effort are lost in this process. Continuous manufacturing is used in many other industries, such as the food industry, and it ensures that products are not exposed to air or other potential contaminants. The process has never been used to make pharmaceuticals. The BARDA Continuous Manufacturing Initiative works with FDA regarding licensing and assuring quality throughout the process. In the long-term, this work will speed medical countermeasure advanced development and manufacturing. It may assist in drug shortage situations and reduce the lifecycle development and operational costs of new products.

PHEMCE has also struggled with product shortages, particularly with seasonal influenza vaccine. The Fill and Finish Network will help during peacetime as well as in pandemic situations. There is transparency in the distribution system related to influenza vaccine where there was none before. CDC has built a secure system with states so that it can be determined where products are in the distribution system and move them through the system. Progress is ongoing regarding barcoding vaccines for the first time.

Other critical drugs are also in shortage. For instance, there was a national saline shortage in 2014. The shortage was so severe that normal saline was released from the SNS. BARDA's crisis-related work with the Institute of Medicine (IOM) was germane in this shortage, as crises

typically increase over time. It is possible, therefore, to take steps to mitigate the coming crisis, such as by conserving, substituting, or rationing products. The electronic health record (EHR) system can help hospitals better manage their inventories so that they can detect problems in their supply chains. This visibility is needed across communities, states, and the nation.

The Fill and Finish Network is now being used for critical drugs beyond influenza drugs and could be useful in the TB world. Additionally, the vendor-managed inventory (VMI) could be useful for TB drugs that experience intermittent supply shortages.

ACET discussed the following topics in relation to BARDA:

- The work that BARDA does on new threats could be applied to old threats. The countermeasures for TB are better than they have been in the past, but it is not clear whether the entire TB enterprise works together.
- The criteria for “diseases of concern” are established by DHS. The determination is based on many factors, such as how many people might die; whether there are available therapies to treat the disease; and other aspects, including the state of the science. TB is relatively well-controlled in the US, although drug-resistant TB has more cases and deaths worldwide and in the US than Ebola.
- TB is a relatively old disease, so there has been little innovation in drugs and regimens. Because of the apparent success of TB and the age of the TB program, TB tends to be dismissed. Old drugs are not profitable, and there is no market incentive to produce them. This problem is mirrored in influenza and with some older antimicrobials. There is always room for stewardship. There is also opportunity in managing the available supply of different therapies to avoid shortages and to ensure that they are where they need to be when they are needed. In the long-term, approaches such as continuous manufacturing may be helpful. At the outset, however, there may not be interest in using continuous manufacturing with inexpensive, generic drugs.
- ACET discussed collaborating with BARDA, particularly in light of significant concerns associated with MDR-TB and extensively drug-resistant TB (XDR-TB). Dr. Lurie suggested that ACET hone in on a problem to solve, given that there are many problems associated with drug shortages, diagnostics, vaccine development, and other areas. BARDA can share lessons learned and connect ACET with other partners. The core services have been built so that other developers and partners can work with them.

## **Latent TB Infection (LTBI) Communications and Messaging**

### **Communicating the Hard to Understand: Latent Tuberculosis Infection**

**Wanda Walton, PhD, MEd**

Chief, Communications, Education, and Behavioral Studies Branch  
Division of Tuberculosis Elimination  
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention  
Centers for Disease Control and Prevention

Dr. Wanda Walton described DTBE’s approaches to communication and education, particularly regarding the terminology of TB. The vision statement of the DTBE Communications, Education, and Behavioral Studies Branch is:

*To strengthen the capacity of health departments and other partners to prevent, control, and eventually eliminate TB through improved communications, information dissemination, education, training, and behavioral studies.*

The terminology of TB has changed over the years:

- Latent tuberculous infection and preventive therapy of latent infection was the terminology used in the original Strategic Plan for the Elimination of Tuberculosis in the United States (1989).
- Screening for tuberculous infection was the terminology used in the first and second editions of the Core Curriculum on Tuberculosis (1990, 1991).
- New terminology was published in 1999: targeted tuberculin testing and treatment of latent tuberculosis infection (LTBI)

The 1999 change was significant in the change from tuberculous infection and in the shift to treatment from preventive therapy or chemoprophylaxis. In a joint statement from the American Thoracic Society (ATS), CDC, and IDSA, it was noted that the change in nomenclature was hoped to “promote greater understanding of the concept for both patients and providers, resulting in more widespread implementation of this essential TB control strategy.”

The change to targeted tuberculin testing occurred to focus on groups at the highest risk for TB and to encourage directed program activities, as opposed to conducting widespread screening for infection. Targeted testing is now used because there are ways other than tuberculin to test for TB. The change also recognizes that the terms “preventive therapy” and “chemoprophylaxis” were confusing. Further, “preventive therapy” was not truly primary.

The change to utilizing the terminology of latent TB infection consistently to differentiate TB infection from TB disease in all materials produced by DTBE has been helpful in providing clear, effective educational materials for healthcare providers and persons with or at risk for TB. Further, the World Health Organization (WHO) is now using LTBI as the accepted term in all of their global guidelines and journal articles.

Challenges remain, however. LTBI versus TB infection helps in differentiating that persons with LTBI are not infectious to other persons. This concept is different from HIV infection, for example. The change has been helpful for educational efforts for persons with LTBI who in the past have been ostracized or stigmatized because of a positive TST.

DTBE does not use the abbreviation LTBI in educational materials for patients and non-clinicians. Use of the full term ensures understanding. The division conducted formative research and evaluation for all of its communication products. Research for LTBI-related products was conducted with focus groups of persons who were representative of the target audiences. The research showed that LTBI “does not roll off of anyone’s tongue.” The communication approach follows Einstein’s theory that “everything should be made as simple as possible, but not simpler.”

Multiple audiences, including healthcare providers, first responders, persons with or at risk for TB, the general public, and policymakers, need information and education about LTBI. Each audience has different information needs, and they have different channels for receiving communication. Further, each audience brings different sets of experiences and skills for interpreting information and different motivations for acquiring information. Therefore, each audience requires tailored information and different communication channels.



The division's approach to training, education, and communication follows a standard process. The process begins with identifying need and progresses to building planning and strategy. Evaluation, including formative, process, outcome, and impact evaluation as appropriate, is conducted at each step. The communications utilize plain language to ensure that the audience understands the message the first time it hears it. The information is organized to serve the audience. The division chooses words carefully and strives to make the information easy to find.

All of the communication materials are available on DTBE's website. The division works hard to keep the site up-to-date, clear, and accessible. The site includes information for the general public as well as materials that were developed for audiences with low literacy levels. Graphics and photographs are included to illustrate concepts and to capture the audience's interest. Educational materials at a higher reading level are provided for patients and non-medical audiences. The materials include tables showing the differences between a person with LTBI and with TB disease. Patient information sheets are provided for treatment regimens. The division conducted extensive testing with patients in clinics to ensure that the information is easy to understand.

In conjunction with partners, DTBE developed "TB 101." This is an online course for healthcare workers. Additionally, the Core Curriculum on Tuberculosis has had a long history in DTBE. The first curriculum was developed in 1990, and the 6<sup>th</sup> Edition is now available. It has grown significantly since its early iterations. The curriculum is available in different formats, including an interactive format that is based on the 6<sup>th</sup> Edition. A slide set has been developed with the curriculum that can be used in teaching environments.

The Guide for Primary Health Care Providers was developed specifically for LTBI in conjunction with the Regional Training and Medical Consultation Centers (RTMCCs). It was originally available only in print, but a mobile application is now available. The *Latent TB Infection: Guide for Diagnosis and Treatment* mobile application makes it easy for healthcare providers to find CDC's latest LTBI recommendations on an iPad, iPhone, iPod Touch, or Android device. When the device is connected to wireless or cellular service, the content is updated automatically to ensure the most up-to-date information is available. To date, the application has been downloaded over 10,000 times. It serves as a ready and useful reference that highlights the main points of key guidelines for diagnosis and treatment of latent TB infection.

DTBE also communicates about LTBI via infographics. One infographic illustrates that TB disease is "the tip of the iceberg." A new Twitter account was launched in April 2015 and has sent over 500 tweets in both English and Spanish on different topics. The tweets direct audiences to the DTBE website for additional information. The account has over 1100 followers from a range of constituencies. The tweets often include graphics, which are more appealing to audiences. The most popular and re-tweeted communications include the following:

- People with latent TB infection don't feel sick, but may still need treatment.
- TB disease rates at all-time low, but TB disease is just the tip of the iceberg.
- Who should get tested for tuberculosis?
- People who have latent TB infection do not feel sick, do not have any symptoms & cannot spread TB to others.
- Treatment of latent TB infection reduces your risk of developing TB disease.

Planning is underway for World TB Day 2016, which has the theme “End TB.” The global Stop TB Partnership is utilizing the same theme and allows different states, regions, territories, and countries to focus on their strategy for ending TB. DTBE is focusing on ending TB in the US with:

- Targeted Testing and Treatment of High-Risk Populations
- Better Diagnostics and Treatment
- Vigilant Surveillance
- Education of Healthcare Providers

When an article has been released, such as the NHANES journal article, or a TB-related event has occurred, DTBE develops talking points with clear, factual information. The talking points are designed for different audiences, such as the media and other groups seeking education. The topic areas focused on:

- NHANES Background, including the study’s history
- Latent TB Infection Prevalence Estimates
- Latent TB Infection Testing and Treatment
- Using TST and IGRA to determine TB infection

LTBI communications materials in development include an infographic specific to the diagnosis and treatment of LTBI. Information about costs will be included in the materials. Regarding the potential coverage of LTBI under the Patient Protection and Affordable Care Act (ACA), a review has been conducted by USPSTF. The TBESC Task Order 12 included study of how to influence private healthcare providers to provide testing and treating for their populations. If the tests are covered, then they are more likely to be provided. Prescribing therapy and providing follow-up is labor-intensive for providers as well. The coverage of LTBI under ACA could be a “game-changer” as testing and the availability of IGRA and short-course therapy could increase the diagnosis and treatment of LTBI by private providers. DTBE will focus communications on primary care providers based on the USPSTF recommendations when they are released.

Several new guidelines related to the diagnosis and treatment of LTBI will be released in 2016. DTBE will develop communication products, including fact sheets, and will use social media and other channels to share them. The division will be prepared for these opportunities.

ACET discussed several issues related to communication and messaging regarding LTBI.

- ACET has previously discussed the importance of conveying the seriousness of having TB infection and whether the addition of “latent” minimizes that message. It is important to convey that a person with LTBI is not contagious.
- The use of LTBI presents challenges in convincing policymakers that TB infection is of consequence. The word “latent” is not a politically expedient term. When it is used, policymakers “go to sleep.” Using the term may amount to false messaging, as LTBI is not really latent, particularly in pediatric populations. In addition to convincing policymakers of the gravity of LTBI, it is important to convince patients of its importance so that they are motivated to take action.
- The word “latent” does not always translate clearly into other languages, which is an important point given the problem with TB in foreign-born populations. “Latent” also has different meaning in reference to viral infections. A term such as “dormant” may be more effective for TB.

- The concepts of TB infection and TB disease are difficult for patients and policymakers to understand. There are valid points for balancing communication for certain at-risk groups, particularly children, for whom latency may not be a relevant term. All LTBI is not created equally. There are different risks for progressing to active disease.
- The strategies for World TB Day did not appear to include specifically targeting populations at risk for TB and developing culturally competent educational tools. Most TB patients are foreign-born and have different health beliefs. Educating these patients has been a barrier.
- There are gold standards for diagnosing other infectious diseases that need to be controlled and eliminated. There is no gold standard for LTBI diagnosis. The nuances of diagnosis should be acknowledged, as well as the “price to pay” if a person is diagnosed with LTBI without absolute certainty. The important goal is preventing active disease, and there are good data regarding the groups that are at risk for progression and how to reach out to them.
- The fact that ACET cannot agree on these issues highlights their complexity.
- The primary audience for education and communication has been the TB public health world, with a focus on TB disease and LTBI. It is important to reach beyond traditional audiences, particularly to primary care providers. Many primary care and public health providers find the guidelines, which are from multiple sources, to be too complex. The messaging needs to be simple for all audiences.

### Status of CDC Reorganization of Global TB Activities

#### **CDC’s New Global TB Branch**

**Shannon Hader, MD, MPH**

Division of Global HIV and TB (proposed)

Center for Global Health

Centers for Disease Control and Prevention

Dr. Shannon Hader provided ACET with an update regarding reorganization of CDC’s global TB work. The global work focuses on developing countries and middle-income countries with high TB burden.

There are an estimated 9 million new TB cases per year in the world. The case detection rate is low, as up to one third of TB cases are missed in a year. MDR-TB is an increasing problem, with an estimated .5 million active cases per year. Over 1.5 million deaths occur from TB every year. TB remains the number one cause of death in the developing world among people living with HIV. Up to two-thirds of TB cases in the US are related to persons born outside the US. Key issues facing global TB control and elimination include:

- Strengthening core TB program activities
- Reaching the “missing” three million cases
- HIV-associated TB
- Spread of drug-resistant TB
- Inadequate resources for the burden of disease

The WHO End TB Strategy has the global goal of ending TB by 2035. If the available tools are used optimally, only a 10% incidence reduction per year can be expected. In order to reach the global goal by 2035, incidence needs to decrease by 17% per year. Innovation is required, particularly related to the challenges of imperfect diagnostics, suboptimal drugs, limited options, and increasing MDR.

CDC can accelerate progress and maximize impact toward global TB elimination. In 2015, most of CDC's global TB portfolio was consolidated into the proposed Division of Global HIV and TB in the Center for Global Health (CGH). This change allows for better coordination across CDC's centers and programs to ensure that information is shared and built upon, leveraging expertise, resources, and in-country infrastructure to unify the mission. Activities can achieve a greater return on an investment by leveraging resources. The new division within CGH will help escalate and elevate the issue of TB within CDC's global health portfolio.

CDC's Global TB Branch includes approximately 40 staff members in Atlanta, Georgia. The team represents diverse experience and expertise in epidemiology, surveillance, infection control, behavioral science, and laboratory expertise. The branch is directly connected to 23 country offices. Each has at least one TB expert to help leverage activities on an ongoing basis.

CDC's TB activities take place in many countries with an existing President's Emergency Plan for AIDS Relief (PEPFAR) platform. These countries have staff on the ground and existing relationships with Ministries of Health (MOHs). There is existing health diplomacy capacity through US ambassadors in these countries as well. The ambassadors help elevate and highlight health issues politically.

Although PEPFAR has a small platform in India and China, the presence is not proportional to the issue of TB in those countries. The Philippines, a country of concern regarding TB, does not have a PEPFAR program. Vietnam has a moderately-sized PEPFAR program, but it is decreasing. CGH is working strategically to build a TB portfolio in these countries. CGH's Division of Global Health Protection has helped with innovative programs regarding MDR-TB control in India.

CDC's global TB strategic approach includes building the evidence base for improved TB control and prevention strategies, translating that evidence into action, and strengthening in-country capacity for implementation. Much of CDC's work in countries where the agency's presence is strong focuses on partners at multiple levels to help countries implement programs to achieve results. CDC's global TB strategic priorities align with the agency's overall priorities to prevent, find, and cure disease. The work requires multiple components in a cycle, and one single activity will not achieve their goals.

It is important for CDC's TB approach to be cohesive, unified, and synergistic across domestic and global priorities. A CDC global TB strategic plan with a programmatic and geographic focus is in development. Country-level coordination is being enhanced, as is technical assistance to ministries and engagement with other partners, such as private sector clinicians and laboratories. Each country will have a TB Operational Plan, which can serve as a transparent way to highlight CDC's time and resources on the ground to make impact over time.

In addition to leveraging CDC's own programs and relationships, it is important to maximize the agency's role globally. Partnerships can be expanded with groups such as the Global Fund, WHO, and the Stop TB Partnership. Additionally, CDC seeks to share lessons learned regarding

global implementation, particularly in global TB and HIV. For instance, CDC has developed with partners a stepwise process toward achieving International Organization for Standardization (ISO) certification for laboratories in Africa. The process thus far focuses on HIV and TB. Further, there is a standardized information system and approach for TB across many countries. The division will always employ metrics and use them for monitoring program management and for continuous improvement.

Several recent milestones in global TB are noteworthy:

- WHO launched its most recent surveillance reports that reinforce the End TB Strategy. The reports indicate that more TB cases are being missed than previously thought.
- The Stop TB Partnership celebrated its first anniversary as an independent entity outside WHO and launched its Global Plan to End TB, an implementation plan that aligns with the End TB Strategy.
- A Global TB Summit was held of the Global TB Caucus for Parliamentarians. The participants included parliamentarians from both developing and developed countries. They came together to reaffirm their commitment to a larger and broader response to global TB.
- The International Union Against TB and Lung Disease held its meeting in Capetown, South Africa. CDC representatives presented approximately 40 different presentations that reflected the diversity of CDC's domestic and global TB activities that will drive the evidence base forward.
- The National Action Plan to Combat MDR-TB is proposed for release in late 2015 or early 2016. Led by the White House, it will include a domestic, international, and research goal.

The division has a number of initiatives planned in the near future, including the following:

- Strengthening national and sub-national TB programs in affected countries: This work includes prevalence surveys and mortality assessments, such as diagnostics and evaluating how they are utilized to change clinical decision-making and care to achieve impact.
- New and more intensive ways to reach the "missing 3 million" TB cases: This work focuses on countries in which the TB epidemic is fueled by high HIV rates. Consolidating TB and HIV activities within the division breaks down the artificial barriers that have existed between the two diseases and will strengthen the entire TB cascade.
- Protecting healthcare workers and patients
- Accelerating response to TB/HIV via "bending the curve" activities in high-prevalence TB and high-prevalence HIV communities.
- Addressing MDR-TB as a crisis and addressing the entire TB cascade.

ACET discussed CDC's global TB activities.

- The division's partners should include organizations such as Save the Children and the United Nations Children's Fund (UNICEF). The division's work leverages PEPFAR resources, and children have generally been left behind for HIV treatment as well as for TB. A new PEPFAR initiative is focusing on pediatric treatment and closing the gaps between adult and pediatric HIV treatment. There are other HIV activities to close the gaps that include specific diagnoses for TB. The issue of pediatric TB should be grown not just in PEPFAR countries, but in all countries where the division works. Active case finding is an important element of this work. Some countries are resistant to preventive

therapy as a strategy, but the issue of exposed children may represent a policy area where it is easier to make progress in policy and implementation. Many young adults who develop TB were infected as children. Prevention in children is a quickly and easily achievable goal.

- TB resources are challenging at all levels. The PEPFAR programs in the countries with high TB rates and high HIV rates have been opportunities for leveraging, as CDC already has a footprint there. There is less flexibility in countries where CDC has a smaller footprint for HIV, such as China, and for countries where there is no HIV footprint, such as the Philippines and México.

As there were no additional questions or comments, Ms. Cole thanked Dr. Hader and dismissed ACET for a lunch break at 12:45 p.m. The meeting resumed at 1:30 p.m. Dr. Dean conducted a roll call and established a quorum of ACET voting members and *ex officio* members.

### NTCA's Updates on New Projects

#### **Robert Belknap, MD**

President, National TB Controllers Association  
ACET Liaison Representative

Dr. Belknap provided ACET with an update on NTCA's projects and activities. NTCA was created in 1995 to bring together leaders of TB programs. The association currently has 366 members representing 47 states, eight big cities, and five territories. The diverse group is divided into three sections: Nurses, Clinicians, and Epidemiology.

Multiple NTCA working groups focus on a number of aspects of TB control, including the following:

- A working group focuses on IGRA. There are difficulties with diagnostic tests, and NTCA saw an opportunity to convene field-level people to comment on data when they are available and to comment on best practices when data are not available.
- A working group is developing a consensus statement on the use of GeneXpert® for removing patients from isolation in the hospital. GeneXpert® received FDA approval for that indication in 2015, but the details and implications of how it might be used were not specified. NTCA organized representatives from APHL and other partners regarding developing consensus recommendations in this area.
- A working group is developing practical guidelines regarding LTBI diagnosis and treatment. This group works in close collaboration with the group that is creating the formal CDC/ATS/IDSA guidelines, which are subject to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria for including evidence. They may not be able to include important aspects necessary for implementing and managing a program for TB prevention in a community or practice. NTCA's working group is creating a companion document for the "how-to" aspect of implementing the guidelines.
- A working group focuses on the issue of healthcare worker screening in the US. There is general agreement that there is over-testing for TB and confusion about previous guidelines in this area. NTCA is working with partner organizations in occupational health, infection control, and US government agencies.



NTCA members face ongoing issues and challenges. Significant challenges are associated with drug shortages and drug pricing. NTCA was able to work with its colleagues to contact the manufacturer and utilize other strategies to respond to the transfer of patent for cycloserine, for example. There is constant risk for necessary TB drugs. A plan needs to be created to protect the field and patients from shortages when there is a single manufacturer or single supplier of a drug. Rifapentine was also temporarily in shortages due to manufacturing changes. NTCA has worked with its colleagues and Sanofi to bridge the gaps of communication and distribution problems. In some instances, there was not an actual shortage of the drug; rather, the distributors did not know how to get the drug.

NTCA has actively participated in supporting and providing input into the National Action Plan for Drug-Resistant TB. NTCA is concerned about how to move forward if the plan is not funded. NTCA has also worked closely with DTBE regarding the US TB Elimination Plan; however, it was not brought forward as a budget expansion. The plan remains critical to achieving elimination of TB.

NTCA responded quickly to a proposal to change 340B drug pricing, which would impact TB control around the country. If the 340B pricing changes, it is not clear how TB programs and states will be able to procure drugs at affordable prices. The association has also been involved in workshops about TB in homeless populations. NTCA adopted the strategy to end stigmatizing language regarding TB. This process is ongoing, and it is important to bring together not only the TB provider community, but also patients and communities affected by TB. NTCA has a large membership of individuals who are willing to volunteer their time and effort to help advance TB elimination in the US.

ACET discussed NTCA's activities.

- ACET suggested conducting a survey of NTCA members to learn, for instance, how many of them use 3HP and how many patients they treat per year. Such a survey could provide a better national picture of TB than any other available source. NTCA likely captures approximately 90% of the active TB disease as well as LTBI in the US. NTCA has an active group that is interested in surveys and collaborative research.
- Ms. Cole read a comment provided by Randall Reves, MD, participating via teleconference, regarding the morning's presentation: "We have a schoolteacher in Denver who has had multiple hospitalizations to manage drug toxicity during her treatment of MDR-TB. Adverse effects include hearing loss, tendon injury, and severe nausea, requiring a feeding tube for medication administration. She would argue, as would we, that we are not doing a good job controlling TB in the US. Transmission also occurred in her family. Could we please stop saying we are doing a great job of TB control in the United States? It is not a reasonable task for healthcare providers to be asking a patient to go through this treatment when it is due to our failure to develop a new, safe, and effective regimen."
- ACET agreed. The issue of MDR-TB will continue to grow. These ideas are related to ACET's discussions regarding messaging. They are moving from control to elimination, and they should think about the strategies that will move in that direction.

## **TB in Congregate Settings**

### **TB Among Homeless Persons**

#### **Sapna Morris, MD, MBA**

Division of TB Elimination

National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

Dr. Morris presented ACET with an update on ongoing DTBE work with persons experiencing homelessness. She noted that the preferred term for this population is “persons experiencing homelessness.” However, for expediency, her presentation used the terminology “homeless persons.”

TB outbreaks among persons staying at overnight homeless facilities have been a longstanding problem, and it continues to challenge TB control and elimination efforts. Uptake of administrative infection control measures has been variable across communities. There is wide disparity in how TB programs address this problem. Some programs are engaged with homeless service agencies, while other programs are not at all connected with those agencies in their communities.

Beginning in 2010 and 2011, DTBE capitalized on relationships with HRSA-sponsored agencies, particularly the National Health Care for the Homeless Council (NHCHC). DTBE also connected with the US Interagency Council on Homelessness (USICH). These partnerships, along with outbreak investigations, led to a proposal for DTBE to host a workshop to connect homeless services agencies and the TB community on the national level. The proposal was funded, and the workshop took place in September 2015.

The workshop was coordinated by Krista Powell and had the mission to discuss and understand barriers and solutions for the implementation of infection control measures in overnight homeless facilities. Some homeless services agencies are reluctant to discuss shelters, as they feel that any resources devoted to shelters are contrary to the aim of ending homelessness. The workshop recognized this potential conflict and focused on how to improve the current situation in these facilities, rather than on ending the problem of homelessness in the US.

The objectives of the workshop included understanding barriers and solutions to implementing administrative controls. Some of these barriers include a lack of consensus, so the workshop worked toward identifying priorities and balancing the priorities, given the range of issues that homeless services agencies address. Approximately 60 people traveled to attend the workshop, and there were over 100 participants. The participants included staff from TB programs, overnight homeless facilities, and other service providers, as well as national and federal partners. The attendees represented 14 states and the District of Columbia and brought a range of perspectives from high-incident and low-incident burden areas. The national and federal partners included government agencies and national organizations such as the Salvation Army.

The topics discussed at the workshop included:

- Partnerships and how to build them better on the local level
- Administrative and respiratory control measures
- Homeless Management Information System (HMIS)
- Education of clients and guests as well as staff members of agencies
- Environmental control measures
- Housing as a healthcare intervention
- Ways CDC and other federal agencies can assist

The workshop provided a unique opportunity to bring together multiple perspectives and diverse expertise in the fields of TB and homelessness. Public health participants were eager to learn more about the US Department of Housing and Urban Development's (HUD) Continuum of Care (CoC) programs. HUD grants include approximately 27 special markers to direct populations in need to assistance with housing; TB is not included as one of the markers. Local CoC programs have some resources to help persons with TB to obtain housing quickly. There are opportunities to build partnerships in this area. Both public health and homelessness experts expressed a need for more cross-collaboration. Partners also requested more updated guidance from CDC on TB and homelessness.

After the workshop, the primary next step is to summarize the proceedings, which will be disseminated widely with the help of partners. Work will continue with partners to foster relationships and facilitate the cross-collaborations from the workshop. NTCA is planning a plenary session for its February 2016 conference that will include speakers from homeless services agencies and TB programs, and webinars are also planned in the next year. Another important next step will be to update the guidelines from 1992. There is a lack of GRADE-level evidence to support rewriting the guidelines, but the guidelines can link to new information, such as information about IGRA. The 1992 guidelines are not obsolete. Many aspects of them are still applicable. Some aspects of TB that have changed should be included to supplement them, however.

DTBE worked with the Curry Center to create a toolkit, which has been well-received. Homeless services agencies commented that the Curry Center Shelter Guide is still used. In an effort to provide more guidance, there was a need for a toolkit for a homeless service provider to learn about TB and for TB providers to learn more about resources for homeless patients. The toolkit includes links to HUD CoC and other providers to help TB programs connect their patients to the services that they need.

USICH was created as an initiative of the Obama administration. One of their main focus areas has been ending veteran homelessness. Approximately 750 communities from across the country have signed on to end veteran homelessness by the end of 2015. Many communities have been successful. The USICH also seeks to end family homelessness and chronic homelessness by 2020. USICH is working to reshape the problem of homelessness as a public health problem. HHS Secretary Burwell will serve as chair of USICH in 2015. Large cities such as Los Angeles, California, and Portland, Oregon, have declared states of emergency based on rising rates of unsheltered homeless persons. NCHHSTP is an important partner in this work.

HUD plans to collaborate with CDC regarding preventing and limiting the spread of communicable diseases in emergency shelter settings and enhancing collaboration with community partners.

ACET discussed TB in populations experiencing homelessness.

- A number of outbreak investigations have utilized WGS. There is clear evidence from multiple methods that recent transmission occurs in congregate settings. The epidemiological evaluation does not yield information about where substances are being used and other potential illegal activities.
- The workshop seemed to focus on the traditional sheltered population. Some jurisdictions have closed shelters, which has helped with TB transmission, but has also created a different kind of homeless population, particularly among foreign-born groups. This new direction brings new shelter settings, such as semi-shelter or church-based facilities. It is important to incorporate the practical consideration of where people sleep.
- The DTBE research agenda includes decreasing disparities, particularly among homeless and incarcerated populations. Research action items should be included on these issues.

## **TB in Correctional Settings**

### **Division of TB Elimination Corrections Workgroup Update**

**Carla Jeffries, JD, MPH**

Division of TB Elimination

National Center for

Centers for Disease Control and Prevention

Ms. Carla Jeffries, the new chair of the DTBE Corrections Workgroup, updated ACET on the recent accomplishments of the workgroup and on the progress on ACET's action items for the workgroup. The Epidemiology of TB in Correctional Facilities surveillance slide set that was created in response to ACET recommendations has been maintained and updated with 2014. This publicly-available slide set will be updated every two years and is available at: <http://www.cdc.gov/tb/publications/slidesets/correctionalfacilities>. New slide sets for non-medical staff have also been posted. The "What Corrections Staff Need to Know" slide set is designed for health departments to use when educating correctional facilities staff on TB treatment and control. A facilitator guide accompanies the slide set, which is available at: <http://www.cdc.gov/tb/publications/slidesets/correctionalstaff/>.

Regarding the TB Cooperative Agreement with funded partners, there is a new requirement for grantees. Correctional liaisons will be responsible for ensuring that a process is in place to foster collaborations between departments and agencies and correctional facilities. Grantees should provide brief summary reports and an annual progress report addressing TB control priorities involving these populations.

Progress has been made on a number of the ACET Corrections Workgroup Resolutions:

ACET RESOLUTION	CORRECTIONS WORKRGROUP RESPONSE
<b>Topic 1: Coordination</b>	
Develop ongoing collaborative partnerships with national and regional correctional organizations.	Partially Initiated: Conversations have begun between DTBE and a number of these organizations. The relationships are not yet truly collaborative, and the division seeks to move toward consistently attending those organizations' meetings and see their representatives at TB conferences. The workgroup solicits advice from ACET on the best ways to build strong partnerships with national corrections organizations.
Conduct a formal evaluation to assess the need for a full-time staff person.	Partially Initiated: The issue has been discussed, but it is unlikely that there will be a possibility in the near future for DTBE to add a full-time, dedicated corrections staff member due to overall staffing reductions.
<b>Topic 2: Surveillance</b>	
Add a question to the RVCT the next time it is updated: History of incarceration in the last (1 or) 2 years.	Partially Initiated: A workgroup will be formed to address revision of the RVCT, and ACET's recommendations for adding a question on the history of incarceration will be considered. Further, work is progressing on possibly revising the instructions or the wording on the "reasons evaluated" variable, which will clarify that testing on intake should be classified as "targeted testing."
<b>Topic 3: TB Case Detection</b>	
Identify methods to improve TB screening, case detection, and medical management.	Fully Initiated: An example of this work is New York City's successful program that has systematically replaced TST with QFT and has been using QFT in all jail facilities since 2012. These processes are well-accepted and efficient. QFT results and information are documented in the Jail Electronic Health Record and are easily retrievable. The program is now planning 3HP implementation in jails to enhance the treatment completion rates for persons with LTBI.
<b>Topic 4: Continuity of Care</b>	
Conduct state-specific analyses of the low rates of TB treatment completion.	Fully Initiated: In 2014, DTBE published comparative state performances on selected TB indicators online using intake data. The division is now working toward the publication of updated state-specific indicators, including a new metric for completion of therapy among those in correctional facilities.

<b>ACET RESOLUTION</b>	<b>CORRECTIONS WORKRGROUP RESPONSE</b>
Identify successful programs for improving continuity of care and TB treatment completion for TB cases.	Partially Initiated: DTBE has begun to identify and describe these programs. Soon, the division hopes to encourage more programs to engage in innovative strategies for continuity of care.
<b>Topic 5: Education</b>	
Conduct a needs assessment.	Fully Initiated: the NTCA Corrections Committee conducted a needs assessment. The Southeastern National TB Center (SNTC) did a poster presentation on the outcomes. There was excellent response to the assessment, with 37 states participating.
Develop, disseminate, and evaluate educational tools.	Fully Initiated: The CDC Correctional Health website was developed with assistance from the DTBE Corrections Workgroup. It includes many resources, in particular a page devoted to a number of overlapping health issues in corrections, including TB. SNTC released its corrections resources webpage, a compilation of in-depth, multimedia tools intended to assist corrections staff and public health programs working in correctional settings on TB control efforts. It also provides links to state-by-state correctional resources. The RTMCCs have developed and presented the "Arresting TB" program, which highlights best practices for recognizing and controlling TB in correctional settings.
Develop TB competency assessment tools.	Fully Initiated: NTCA has developed core competency tools that are available and downloadable.
<b>Topic 6: Funding</b>	
Partner with key stakeholders to leverage existing and future resources for TB prevention and control in correctional and detention facilities.	Ongoing: The workgroup asks ACET for advice regarding determining specific stakeholders for engagement and regarding which resources might best help them. National surveillance data indicate that cases diagnosed in residents of correctional facilities are not necessarily decreasing as a percent of total cases of TB annually. There is a need, therefore, to focus on key stakeholder partnerships.



In the three years since the resolutions were passed, the majority of the items are now fully initiated. The ACET resolution pertaining to exploring the possibility of establishing a central system to obtain completion of treatment information has been deferred. The division has also deferred the resolution on exploring the possibility of evaluating the effectiveness of Cure-TB and TB-Net from a correctional standpoint.

**The DTBE Corrections Workgroup seeks advice and input from ACET regarding:**

- ☐ The best ways to build strong partnerships with national corrections organizations.
- ☐ Determining specific stakeholders for engagement and regarding which resources might best help them.

**Maria Galvis, BA**

Division of TB Elimination  
National Center for  
Centers for Disease Control and Prevention

Ms. Galvis described a program in Arizona that has been successful in pursuing continuity of care. Approximately 4% of TB cases in the US are diagnosed in a correctional facility. Approximately 25% of TB cases in Arizona are diagnosed in a correctional facility. Arizona is a border state, and TB at the US-México border is challenging. In 2014, 75% of correctional cases of TB were reported by US Immigration and Customs Enforcement (ICE) while the individuals were in custody.

Arizona engages in a number of correctional activities related to TB, including the following:

- The state provides technical assistance and consultation to local health departments as needed.
- Local health departments and the state serve as TB consultants to local correctional healthcare staff when requested. On occasion, infection control nurses call the health department to request information about screening or isolation situations. DTBE is working to strengthen these relationships and provide assistance as requested.
- A new full-time epidemiologist at the local health department in Pinal County, from where approximately 90% of correctional cases are imported, serves as a local correctional liaison, maintaining close relationships with local correctional staff. The epidemiologist serves as the local point of contact for DTBE and provides guidance regarding reporting cases as well as conducting and managing contact investigations in correctional facilities. Further, a State Nurse Consultant has been designated as the State Correctional Liaison. She works with cases that are transferred or referred in and out of Arizona. She also provides guidance regarding case management and treatment recommendations.
- State TB staff and Pinal County health department staff participate on monthly conference calls to review correctional TB cases.
- The state has been working on interviewing TB cases, especially smear-positive cases. Local county staff have been trained to conduct interviews at correctional facilities. These interviews are crucial, as they also provide education regarding the importance of continuing TB treatment after a patient is deported. Staff have also been able, at times, to interview family members and household contacts. The county continues to conduct this activity when a new case report is received. Approximately 80% of smear-positive cases are now being interviewed.

- In late 2014, a group of partners convened to provide TB education to correctional healthcare staff. That training will continue to be provided at least once or twice per year.

Other activities focus on continuation of TB care and binational cases include the following:

- Some binational cases are enrolled in a “Meet and Greet” program, which was developed in 2007 by the states of Arizona and Sonora, México to ensure the continuity of care of TB cases and the completion of treatment for confirmed TB cases. The program arranges for a Mexican National with active TB disease who is being deported by ICE to be met by a Sonoran public health provider at the Nogales Port of Entry. The program’s goal is to complete approximately ten of these “meet and greets” per year.
- Arizona’s binational disease notification system is called the Medical Electronic Disease Surveillance Intelligence System (MEDSIS). The local health department can use the system to work with México regarding binational cases.
- Cure TB and TB Net have been included in MEDSIS. Both national organizations can have access to the system to update referrals and to communicate. Both programs have strongly contributed to Arizona’s success to increasing completion of TB treatment among correctional cases.

ACET discussed aspects of TB in correctional settings.

- ICE has its own facilities in some areas, but in other parts of the country, ICE detainees are held in contract facilities. Some of the continuity and movement of people have been problematic. It is important to maintain relationships and communication through the challenges associated with the movement and transfer of correctional cases. With the help of binational organizations such as Cure TB and TB Net, the situation can improve.
- Detention facilities in which ICE is not the medical authority provide their own healthcare, and there is not an automatic notification to trigger ICE to collaborate with the health department regarding continuity of care. Health departments are encouraged, whenever they are working with local detention facilities, to determine what entity has custody of the patient. Then it is possible to coordinate with the facility and care agency with custodial authority.
- The data from Arizona showing that a significant proportion of TB patients in correctional facilities are in ICE custody at the time of diagnosis may be the result of an over-classification of “ICE custody,” as custody is reported by health departments and is not verified. A separate analysis of Arizona data showed that 50% of the reported TB patients were truly in ICE custody.
- Regarding outreach to national correctional organizations, ACET suggested seeking out the private, for-profit sector that provides care within prisons and jails. Other potential partners include groups such as the Fortune Society, who work to improve conditions in prisons. Each Regional Training and Medical Consultation Center (RTMCC) has a corrections point of contact. That person could help link DTBE to national organizations. The National Commission on Correctional Healthcare (NCCHC) is another potential partner.
- The potential for 3HP in the correctional setting is significant. BOP is having an excellent experience with the regimen, with 92% of participants in a pilot study completing it. Correctional healthcare providers are enthusiastic about 3HP. It is a great opportunity for prevention in corrections and for interfacing with the homeless.

With no additional questions or comments posed, Ms. Cole dismissed the group for a break at 2:50 p.m. The meeting reconvened at 3:07 p.m. Dr. Dean called the roll and established that a quorum was present and the meeting could proceed.

### **Next Steps for Reporting**



#### **Thomas R. Navin, MD**

Chief, Surveillance, Epidemiology, and Outbreak Investigations Branch  
Division of Tuberculosis Elimination  
National Center for  
Centers for Disease Control and Prevention

Dr. Navin updated ACET with DTBE's steps toward implementing national LTBI reporting. The antecedents to CDC's plans for LTBI reporting are as follows:

- NTCA conducted a survey of TB programs. It revealed that there is substantial support for national LTBI reporting if the reporting system is efficient and effective, and resources are adequate.
- The ACET LTBI Reporting Workgroup provided input on June 2, 2015.
- TBESC is about to transition from comparing LTBI diagnostic tests to a new focus on improving LTBI testing and treatment and on the LTBI "Treatment Cascade."

The ACET LTBI Reporting Workgroup provided six points of a proposed national LTBI reporting system:

- The goal is to report all TST and IGRA test results
- Report the reasons the tests were ordered
- Collect demographic information, risk factors for progression, and previous treatment history
- Collect provider and patient contact information
- Report treatment acceptance and the regimen that was offered
- Report treatment completion or non-completion

CDC proposes a three-pronged approach to the technical aspects of LTBI reporting:

- Develop a robust, clinic-based LTBI patient management system, which will have a function to automatically report data to CDC. This effort is led by the TBESC and is called "S.T.E.M.S."
- Work with TB programs that currently have electronic LTBI reporting systems and develop data transmission standards so that any program that has electronic data and is willing to share it will be able to do so.
- Develop a simple, online form for TB programs that have reports, but no reporting system. This option will resemble the eRVCT.

The first prong will be pilot-tested soon. It has various modules and is designed to make patient management easy. It will collect vital information for LTBI surveillance. Regarding the second prong, a few states have electronic systems in place. Most of them are willing to share the data. The technical challenge is associated with consolidating the disparate data into a unified system. The eRVCT-like prong will be a CDC-provided tool for programs to enter their own data. The critical federal roles in national reporting are to define minimum data elements to be reported and to create a structure for a national surveillance system that has descriptive analytics and provides quality assurance and standardized reporting.

The NTCA Executive Board discussed this approach and noted that many programs have electronic laboratory reporting information but do not have a means for tracking it. The eRVCT-like prong will provide a needed tool. Additionally, partners that conduct laboratory reporting have offered to consider their electronic laboratory reporting mechanisms. It is challenging to use these mechanisms as a sole data source for national reporting. For example, the mechanisms collect some demographic information, but they do not collect information on whether the individual is foreign-born. That information is critical for TB surveillance. The mechanisms also do not collect why the tests were ordered or risk factor data. The existing electronic laboratory data indicate interesting trends and discrepancies, but these effects could be due to the persons being tested, not because of underlying infection rates. DTBE is considering a way to collect important data, but it may not solve the problem.

DTBE is focusing on defining the Minimum Data Elements for reporting. In collaboration with TBESC partners, 49 elements have been developed. Each element has been defined, and it has been established how they will look in the electronic form. The division has created a draft of a standardized report form as well.

There are strategic issues associated with addressing national reporting. The “LTBI Prevention Cascade” normally focuses on the last two elements: persons who started LTBI treatment, and the treatment completion rate. Historically, treatment completion rates are approximately 50%. TBESC has achieved close to 80% completion. Strategically, however, it is important to look “upstream” at the number of people in a community who have LTBI, or are at risk for LTBI or progression to TB, and who should receive targeted testing. Then, it is important to know the persons who are engaged in care, have been tested for LTBI, and who have received an LTBI diagnosis or are ruled out for TB. Within that group, an assessment can be made of who has started and completed TB treatment. In order to have an impact on TB prevention, a community-wide picture of targeted testing is needed. TBESC is focusing on:

- Publicly available data sources, including the US census, NHANES, Global Information Systems (GIS) mapping, surveys, and perhaps billing information
- Health department TB clinics for individual data

The next step will be to collect information from other TB care service providers, such as other public health clinics, Federally-Qualified Health Centers (FQHCs), community-based organizations, and private providers.

The proposed system responds to the ACET workgroup conclusions in the following ways:

- Regarding reporting of all TST and IGRA results, it is important to focus on high-risk groups for targeted testing. The NHANES results show a great deal of testing for LTBI among low-risk groups.
- The reason for ordering the test is essential to capture.
- Similarly, demographic information, risk factors for progression, and previous treatment history are essential. In addition, risk factors for infection should be captured to ensure adequate focus on high-risk groups.
- Provider and patient contact information will not be part of a national reporting system, but would be important for a case management system.
- Treatment acceptance and regimen are critical.
- Treatment completion or non-completion is critical.

DTBE also adds two elements to the reporting system:

- Collection of information on adverse effects, especially serious adverse effects. An important lesson was learned from 2RZ, which showed no indications of serious adverse effects in clinical trials, but expansion showed unexpected death from the regimen.
- Ideally, a national system could be used to detect when people who are tested for LTBI progress to active TB. The numbers are too small for this detection now, but a national system could make it possible.

ACET discussed the LTBI reporting system.

- It can be problematic to report at the Zip code level when patients are neither sick nor contagious. Privacy issues could inhibit reporting. A large volume of data is likely to be reported. A large number of people in the targeted group receive purified protein derivative (PPD) skin tests in large hospitals and clinics. Reporting could present a burden, especially given the number of elements, if the form cannot be automated for download.
- TB is a reportable infectious disease, but LTBI is not currently reported to CDC in any form. CDC is not expected to mandate reporting, and resources are not available to assist in reporting. CDC's role is to provide a receptacle and a mechanism to receive reports from the programs that do their own reporting.
- ACET supported moving forward with piloting the reporting form in TB sites without waiting for the electronic case management to be fully operational.
- The STEMS case management system should be integrated into the EHR. Asking providers to use separate systems is not likely to work. Additionally, the data quality from the 2014 LTBI reports was poor. In order to get a full picture of LTBI, a lot of pen-and-paper reporting is needed. There are gaps in the reporting system. The reporting may need to separate the highest-risk populations that public health should pay the most attention to.
- It will not be possible to eliminate TB in the US without addressing LTBI. It was suggested that only patients who are positive should be included to lower the burden on the reporting system. The approach is consistent with other reportable disease frameworks. However, if the system only focuses on positive test results, then it will not be possible to address the question of how many people are not being tested. Further, it may be problematic to

begin the system with only positives and then revise it in the future to include more elements.

- The system is likely to be useful, particularly for examining discrepancies between where LTBI testing is conducted and where active cases are. The system will allow for enhanced targeting of LTBI testing. The system needs to capture more than only positives because it is important to know where the testing is being performed.
- The number of variables in the system is still quite high. It may be preferable to select only a few variables for immediate focus. Many variables on the prevention cascade can only be estimated from models and will not come from programmatic data.
- There are a number of competing interests in TB and in public health as a whole. The next step in operationalizing the system might focus on the early adopters at pilot sites to provide a proof of concept. The system can then grow larger. If the system is initially made open to anyone who wants to participate, then there is a risk of haphazard participation with reporting bias.
- The electronic laboratory report (ELR) is a critical element of this work. It will be relatively simple to create and maintain a system to share ELR results with health departments. Positives and negatives can be reportable, and health departments can follow up as their resources permit. The data from laboratory sources could be combined with other tools, such as special studies or surveillance work. Ideally, health departments will receive ELRs and integrate them with their own data streams.
- ACET emphasized the need to focus on the problem that they are trying to solve. Given the resources and time needed to report, it is important to indicate how the efforts advance the field. Often, public health is good at collecting data and not as good at translating it into something specific.
- At the local level, it will be problematic to use a separate system for LTBI reports that cannot show when an individual with LTBI becomes a TB infection case. The reports should be able to be matched to case registries to learn this information quickly. The Council of State and Territorial Epidemiologists (CSTE) is not opposed to a national reporting system, but the group feels that it is too early for LTBI to be a reportable condition.
- Local jurisdictions should determine what populations in their area have a high prevalence. These populations may vary from place to place. There is not a single list of risk groups that applies everywhere.
- If USPSTF gives a high grade to LTBI screening, it may provide an opportune moment to have tools ready for providers so that they can learn whether they are testing the right people and responding appropriately to positive results. Providers will not track the testing unless they choose it as their clinical quality indicator for TB.
- Risk categories in LTBI collection should be included to identify individuals at highest risk for TB disease, whether their LTBI test results are positive or negative. The tests are not perfect. A large percentage of persons with HIV infection develop TB disease and are never LTBI positive. It is important to quantify high-risk persons. Modeling requires quality data for estimating the volume of persons with LTBI, estimating the costs of testing and treating people who have not been tested or treated, and projecting achievements of TB elimination.

## TB Elimination Facilitated Discussion

### **Philip LoBue, MD**

Director, Division of Tuberculosis Elimination  
National Center for HIV/AIDS, STD, Viral Hepatitis and TB Prevention  
Centers for Disease Control and Prevention

Dr. LoBue led ACET in a discussion of steps that are needed to move toward TB elimination in the US. 2019 will mark the 30<sup>th</sup> anniversary of the original TB Elimination Plan. The current iteration of the National Elimination Strategy came from a 2000 IOM report. The six goals (or strategies) of the strategy are to:

- Maintain control of TB
- Accelerate the decline
- Develop new tools
- Reduce the global TB burden: CDC is a partner in this huge global effort
- Mobilize and sustain support
- Track progress

Accelerating the decline of TB is critically important, as eliminating TB relies on this strategy: *Advance toward TB elimination through targeted testing and treatment of persons with latent TB infection, appropriate regionalization of TB control activities, rapid recognition of TB transmission using DNA fingerprinting methods, and rapid outbreak response.*

In particular, targeted testing and treatment of persons with LTBI is important. There are also persistent issues with outbreaks. It is important to recognize and respond to them quickly. Outbreaks occur in a variety of populations, but nearly every outbreak with which CDC assists involves homelessness, correctional facilities, substance abuse, or a combination of the three. Recent analyses show that reactivation represents the majority of cases in terms of origination, but these outbreaks pose significant burdens on state and local health departments. Because of this burden, the state and local entities are unlikely to be able to focus on elimination activities associated with enhanced targeted testing. As long as outbreaks continue to occur, they will be an impediment to targeted testing and treatment for LTBI.

Two issues need particular focus:

- Reactivation of LTBI, which is predominantly foreign-born: it is the area of biggest potential impact, but it is a daunting task, given NHANES data. There is no new vaccine or new strategy to address this issue.
- Recent transmission and outbreaks: they should be prevented or better contained. The populations experiencing outbreaks include the US-born, homeless, incarcerated, and substance abusers.



ACET discussed several facets of TB elimination.

- The NHANES data show the prevalence of untreated TB infection. There is still an influx of incidence that has not been stopped. One of the most important questions to ask is how the people with TB infection were missed and how they could have been discovered earlier.
- For some time, it was believed that foreign-born persons are most likely to develop disease in the first two years of residency; now, an overwhelming number of cases are among people who have been in the US for more than 10 years:
  - In order for public health to make an impact on reducing cases, individuals who have been in the US for a long time should be targeted. This approach is less efficient, however, because of the large denominator.
  - The greatest risk factor for TB is country of birth, but that information is not routinely collected in most healthcare settings. ACET discussed opportunities to make country of birth part of meaningful use requirements. If not, then there may be opportunities to work with the largest of the EHR providers, Epic, in this area.
  - Many legal immigrants do not have access to healthcare in their first five years in the US, when their risk for active TB is the highest. TB testing and treatment should be encouraged in primary care, but this group is locked out of primary care because of a lack of insurance coverage.
  - It is also important to consider global mobility. People want to travel and are very mobile themselves, and they also frequently host visitors from outside the country.
  - When the data are used for cost-effectiveness analysis, it shows that only the foreign-born, not the US-born, population should be tested. Further, all foreign-born persons should be tested, regardless of how long they have been in the US. This population represents millions of people, which is significantly more than the TB world is accustomed to addressing. This level of testing is beyond the reach of health departments. CDC needs to engage others effectively to help with this burden.
- Recent immigrants are tested in a variety of settings, but individuals who have been in the US for a long time are less likely to visit the health department. The only way to capture these individuals is to educate primary care providers, especially family physicians:
  - These providers often do not have a great deal of knowledge about TB and the different tests for it.
  - It should be feasible to add TB testing to routine blood screening.
  - As active TB disease decreases, expertise and knowledge about TB will naturally decrease. TB infection prevention will have to be addressed at the systems level. Collecting risk automatically can lead to best practices alerts and automatic testing.
  - Health departments cannot do this work alone, but few private practitioners do LTBI therapy.
  - If USPSTF approves LTBI testing, then the physicians should be educated on why it was approved and why it is important. If testing is not approved, then the TB community should understand why and take steps to collect the data that will be needed to convince USPSTF. There is skepticism regarding whether high-risk populations are seen at primary care sites.
- There is a paucity of real, actionable data on how to engage providers. Other funders, such as NIH or TBTC, could be leveraged to support operational research to fill the “know-do” gap.

- Other federal agencies should recognize the roles that they will play and the need to generate funding or strategies for TB elimination.
- While there is a conundrum associated with testing and treatment among populations of substance abusers and the homeless, there are simple solutions for incarcerated populations, which are already screened for TB. Most facilities, save short-term facilities, treat for TB. The public health community should strongly support the implementation of 3HP in corrections settings.
- Updated LTBI guidelines are needed that liberalize treating foreign-born individuals who have been in the US for greater than five years. Self-administered 3HP should also be addressed, and there should be additional trials of 1HP or 2HP.
- WHO is prioritizing the notion that TB infection has to be addressed to reach zero TB. TB infection has been deemphasized and must be reemphasized. The work can begin with AHRQ funding incorporation of TB into the EHR and with partnerships with industry. Systems need to see the cost-effectiveness of implementing strategies that are known to be effective.

### Wrap-Up Discussion

Ms. Cole reviewed the major messages from the day's presentations and discussion.

#### NCHHSTP Update

- There was only a 1.5% decline in TB in 2014, the smallest decline in the decade. This statistic is important in the move toward TB elimination.
- There are health disparities in TB, and HIV may offer lessons learned about disparities and SDOH as well as funding incentives for testing.
- The atlas is a useful resource.
- There are activities in TB-HIV, and there are opportunities for linkages between TB and hepatitis B, especially among Asians.

#### DTBE Update

- The 2016-2020 strategic plan has a target goal of 3.0 cases per 100,000 population now, and a 2020 goal of 1.4 cases per 100,000 population.
- The estimates of LTBI are important, as the "bottom of the iceberg" is critical for TB elimination.
- The DST in California was funded.

#### DTBE Research Agenda Update

- DTBE provided a summary of the research priorities and research inventory.
- There are opportunities for ACET to identify gaps in the research topics and suggest how to fill those gaps.
- ACET is asked to assist DTBE in prioritizing research areas with the understanding that a new initiative will require that another initiative will not be funded.
- There may be other resources for operational research.

## BARDA

- ACET requested this presentation to learn what BARDA does and to determine opportunities to collaborate and interface with BARDA.
- MDR-TB and XDR-TB are tangible concerns. Drug-resistant TB is considered a Category C bioterrorism agent. XDR-TB is a national security threat.
- ACET can make recommendations regarding including TB on the DHS list of agents that present a true material threat.
- BARDA has core services and facilitates medical countermeasures. TB drugs may not be included in a stockpile. A coordinated plan is needed in this area.

## LTBI Communications and Messaging

- ACET had a fruitful discussion regarding the term “LTBI” versus “TB infection.” There is a mix of opinions among ACET regarding the proper terminology. Rationale was provided for maintaining the term LTBI. Conversely, there was discussion regarding whether the message is accurate and whether LTBI is truly latent.
- It may be preferable for patients to refer to LTBI and providers to refer to TB infection, but this approach may be confusing.
- ACET will discuss potential next steps and recommendations.
- DTBE has posted a variety of useful materials.

## CDC Reorganization of Global TB Activities

- Dr. Hader presented an overview of how this integration is taking place and where initiatives are.
- ACET does not want domestic TB to be lost in the mix of the consolidation. It appears that there are interfaces and ongoing work to eliminate domestic TB by working globally, particularly in the 22 countries where CDC has a strong footprint.
- Pediatric TB is critically important, and partners such as UNICEF and Save the Children are vital.

## NTCA Update

- NTCA provided updates on IGRA guidelines and work on LTBI.
- NTCA is working on a companion document for upcoming guidelines.
- NTCA has reach into a number of states and large jurisdiction.
- ACET suggested that NTCA survey its membership regarding testing, treatment, implementation of 3HP. This information could inform decision-making.

## TB in Congregate Settings

- A productive workshop was held with multiple agencies and stakeholders regarding TB among persons experiencing homelessness.
- ACET should consider the HUD Continuum of Care.
- ACET heard a status report on progress on recommendations from the ACET Corrections Workgroup. Thirteen of ACET’s recommendations have been fully initiated.
- A combined group, the Congregate Settings Workgroup of ACET, will be convened to consider homeless and incarcerated populations.

### Latent TB Infection Reporting

- ACET heard an overview of the proposed reporting system.
- The system will be voluntary and will allow clinics and health departments to submit ELRs into it.
- The volume of testing will need to be managed. Looking only at positive test results is a potential approach.
- This system is a direct result of an ACET workgroup recommendation. ACET appreciates the follow-up on its recommendations.
- Existing sources of data should be considered as well.
- EHRs are being used in different settings to alert primary care providers regarding testing.

### TB Elimination Discussion

- ACET discussed action items that will move toward TB elimination.
- Treatment (pills in bellies) is critical for TB elimination.
- Public health must engage with private providers.
- The USPSTF rating for LTBI testing will be important in many areas.
- There may be other funding sources for operational research.

A motion was properly placed on the floor by Dr. James Sunstrum and seconded by Dr. Michael Lauzardo to adjourn the ACET meeting for the day. **The motion carried unanimously with no abstentions.**

With that, ACET stood in recess at 4:52 p.m. on December 15, 2015.

### **Call to Order / Roll Call**

The second day of the ACET meeting began at 8:31 a.m. on December 16, 2015. Dr. Dean greeted the group and reminded them that ACET meetings are public, and that all comments made during the meeting are a matter of public record. She conducted a roll call of ACET voting members, *ex officio* members, and liaison representatives. There was a quorum of ACET members.

### Business Session

### **Motion to Accept Minutes from June 2015 Meeting**

Ms. Cole raised an item regarding the minutes from the June 2015 ACET meeting. Regarding ACET's discussion of action steps to recommend to CDC on TB elimination, page 12 of the minutes under "2. TB Risk Assessment" states "perform pharmacy-based risk assessment with subsequent IGRA testing." The rationale for the proposed intervention is stated as "develop materials to educate pharmacists on conducting risk assessments of patients who present with prescriptions for TB medications."

Ms. Cole asked why, if a patient is already on TB medications, the pharmacist should conduct a risk assessment. A motion was properly placed on the floor by Dr. Lisa Armitige and seconded by Dr. Michael Lauzardo to delete the proposed intervention, “perform pharmacy-based risk assessment with subsequent IGRA testing,” and its rationale from page 12 of the June 2015 ACET minutes. **The motion carried unanimously with no abstentions.**

### Advice from ACET

Ms. Cole explained that ACET meetings are a forum for ACET to discuss requests from CDC and DTBE for recommendations.

**DTBE Research Agenda: ACET was asked to consider the agenda, identify gaps, and make additional recommendations.** The DTBE research priorities are:

- ☐ Decrease incidence of TB infection
  - ☐ Decrease morbidity and mortality from *M. tuberculosis*
  - ☐ Decrease health disparities across groups affected by TB (including SDOH)
  - ☐ Conduct surveillance for adverse events and treatment outcomes (including post-marketing surveillance)
- 
- Increasing the ability to treat LTBI is a primary goal. The incidence of LTBI must decrease and more patients must be treated for LTBI, but health departments are tapped out. Strategic approaches to screening and treating people for LTBI are needed in order to achieve the research priorities and goals. Providers who are not part of the health department system, such as FQHCs, foreign-born practitioners that treat a great deal of foreign-born populations, and other providers who work with high-risk groups, must be incorporated. There is not a clear path for increasing the number of people treating LTBI successfully and safely. What needs to be done the most, and what the least is known about, is engaging providers in an evidence-based way that will lead to more treatment of LTBI beyond health departments. More operational research should focus directly on engaging providers to treating LTBI. TBESC could go in this direction with efforts to optimize LTBI therapy. Other existing initiatives could be focused on operational issues. Qualitative research collects different types of data, and this work should move in that direction. Few health departments will have capacity to conduct the research, but some will. CDC could release Requests for Proposals (RFPs) for research and demonstration projects within TBESC but also outside that structure.
  - Decreasing the incidence of LTBI is one issue. Decreasing the prevalence of untreated LTBI is another issue. The research agenda should include both aspects of LTBI. They require different strategies. Partners can help in communicating with private providers, many of whom are involved in organizations such as the American Academy of Pediatrics (AAP) and the American Association of Family Practitioners (AAFP), as well as internal medicine organizations. These clinicians and the organizations that represent them can be mobilized to accomplish these goals.

- Partnerships with liaison organizations should be mobilized. FQHCs and community health centers are important, but large organizations such as Kaiser are also important. Health departments need to reach out to the private sector, and they need help doing this work correctly. Larger investments are needed in demonstration projects, as are occurring with hepatitis C.
- LTBI testing could be a quality indicator. Federal organizations and health maintenance organizations (HMOs) have interest in these indicators. If LTBI testing is a quality indicator, then there will be more interest in incorporating it into the EHR.
- Behavior change is difficult. There are already challenges, as guidelines have not been released and there are no clear recommendations to disseminate. Without these elements in hand, it is challenging to take further steps. When the recommendations are complete, they will need to be interpreted for physician audiences.
- Health departments want to communicate with providers about LTBI testing, but it is difficult to prioritize that work when there are other priorities in active TB cases. LTBI testing is a new activity, and it requires new funding.
- Increasing the funding envelope is necessary to achieve many of the priorities. It will be important to be clear in terminology. For instance, the lay press and policymakers do not know the difference between infection and disease. The connection needs to be made without inspiring fear so that additional funding can be secured. Research is part of the effort, but in order to conduct research beyond direct patient care or new drugs, there must be understanding of TB infection. Implementation and social science research funding requires that understanding.
- The DTBE research priorities may be too broad. The first priority should be to decrease prevalence of undiagnosed / untreated LTBI.
- The Bureau of Primary Care within HRSA is a potential partner for operational research or demonstration projects, working with FQHCs. There could be contests or other approaches to encourage new ways of thinking about engaging providers and patients. These issues might affect the Essential Components of a TB Program. Public health needs the appropriate toolkits to begin the engagement process.
- Primary care provider organizations have a number of unfunded mandates. Even when the mandates are funded, it is difficult for the providers to fulfill all of them. Providers could be approached regarding LTBI testing from the perspective of a patient-centered medical home. That platform allows for preventive health screening to occur in the context of a multidisciplinary care team. A consultation with different representatives from primary care groups could yield qualitative information about the challenges of doing this work.
- Issues of messaging and terminology affect not only providers, but also the lay public, particularly regarding LTBI. Other diseases may have been in similar situations and leveraged a public relations angle to ensure that the public understands the differences between TB infection and TB disease. The terms are used differently even within the TB community. If the TB community is not consistent, then other professionals, the public, and policymakers will continue to be confused.
- CDC could reach out to primary care organizations by initiating research with the patients that the providers see and capitalizing on opportunities that may already be in their practices. Initiating that research would open the door to collaboration if the research indicated that the practices are successful places for LTBI treatment. TBESC focuses on health departments and their local collaborators. Operational research to identify best practices for health departments is important, but CDC should move outside TBESC and reach out to professional organizations to identify opportunities for LTBI treatment in current practice.

- There is a sense that things are going well in TB and a lack of a sense of urgency. ACET's title refers to the elimination of TB. There are more TB deaths every year than the goal for total number of TB cases. It would be helpful for the CDC Director's office to address that the TB Elimination Plan failed, describe why it failed, and specify what is needed to address the problem of TB. The goal for 2015 was to have fewer than 400 TB cases, not to have more than 400 people die of TB.
- AHRQ is interested in research on innovative ways of encouraging clinicians to adopt appropriate behavior. AHRQ is not focused specifically on TB but could be interested in research on generalizable principles, using TB as a model.

A motion was properly placed on the floor by Dr. Michael Lauzardo and seconded by Dr. Ana Alvarez that ACET recommend that CDC explore options to increase operational research to build an evidence base of best practices to increase the capacity within and outside health departments to increase the number of providers to reduce the prevalence of untreated LTBI in the US. **The motion carried unanimously with no abstentions.**

Dr. Starke offered a footnote, emphasizing that availability of medications is a significant issue. In some jurisdictions, health departments will not provide medication to persons who are not part of contact investigations. Without insurance, LTBI treatment is out of the reach of many populations. The medication supply and how it will be paid for should be addressed.

Dr. LoBue thanked ACET and said that the recommendation will allow DTBE to explore possibilities internally with existing structures. DTBE can discuss possibilities with other federal agencies as well. The USPSTF recommendation will be important, as it will carry weight with primary care providers and HRSA.

**DTBE requested ACET's advice regarding improvement in two areas:**

Reactivation of LTBI among foreign-born populations

Recent transmission / outbreaks among US-born incarcerated, homeless, and substance abuse populations

- Some providers avoid providing LTBI treatment for budgetary reasons. Since most TB is reactivated and not related to contact investigations, it should remain a high priority for public health to treat all LTBI when it is identified.
- If the larger number of TB cases are coming from individuals who have been in the US for longer periods of time, then that group is worth consideration. More information is needed about the individuals who have been in the US for over five years. Screening and treating recent immigrants represents a quickly and easily achievable goal with high yield. This approach is showing decreases in the number of TB cases, especially among persons who were screened overseas before coming to the US. There may be subgroups within the large group of individuals who have been in the US for some time who could be targeted for testing. Perhaps CDC data about foreign-born individuals who have been in the US for five years or longer could be analyzed to determine whether there are subgroups that are more likely to break down with disease. These groups could be targeted not only for testing and treatment, but also for messaging.



- To achieve elimination, the boundaries of testing must be stretched to include groups who are progressively less at risk. The process then becomes less efficient. Epidemiology shows that people with additional risk factors for progression should be given higher priority. The data suggest that case rates are higher among people who have been in the US for a shorter length of time; however, individuals who are now breaking down came to the US five or more years ago. Some years ago, ACET recommended that all people coming to the US on visas that would allow stays of six months or longer should be screened for TB overseas prior to that migration, utilizing the most recent technical instructions. Millions of people come to the US and are not screened for TB. While there is a bolus of people in the US for some time, people are still coming into the country, and the migration should be addressed at both ends.
- The recommendations are being rewritten, and the time cutoff will be addressed. Regarding overseas screening, the Division of Global Migration and Quarantine (DGMQ) requested funding through the CARB initiative to begin piloting that type of work. Significant regulatory issues need to be explored. Further, DTBE is considering the possibility of a joint project between DTBE, DGMQ, and the proposed Division of Global HIV and TB using CDC's Innovation Funding to study the potential for piloting overseas LTBI testing and treatment with short-course regimens.
- There are challenges, including costs and practicality issues, associated with reaching the larger pool of foreign-born persons who have been in the US for a longer time. The charge given to ACET is to provide guidance regarding TB elimination goals. In order to improve in the area of LTBI reactivation among foreign-born populations, those groups must be targeted. The costs may be higher, but it is not ACET's role to calculate the practicality issues. The council provides guidance on achieving elimination goals.
- The push-pull between clinical concerns versus public health mandates remains a significant issue in TB and may not be an issue in other diseases that have separate clinical and public health structures. If ACET's vision is elimination, then it should make those recommendations. If guidance is clear, then TB controllers and the TB community can work at the individual level.
- If achieving elimination goals will require more money, then ACET should say so. Working within the existing budget will not accomplish TB elimination.
- The foreign-born population that has been in the US for some time is critical to target, but it is also important to provide specific guidance. The pool of data regarding foreign-born individuals who have been in the US for more than five years can be analyzed to determine who is most likely to break down with disease to target and refine interventions. Everyone should not be tested, but trends that emerge within that data should be a point of focus now.
- Persons born in México represent the clear majority of reactivated LTBI among individuals who have been in the US for longer than five years. Different data sets can be combined to learn about individual risk groups. People with additional underlying medical problems or other risks for progression are at higher risk. It is possible to model potential impact from focusing on certain groups.
- NEEMA projects have studied the impact of testing all foreign-born persons versus the impact of testing only foreign-born persons with co-morbidities. It is clear that TB elimination cannot be achieved if only foreign-born individuals with medical co-morbidities are tested. The approach may seem more feasible, but it is not. These populations may need to be prioritized in certain settings, but based on the data and modeling, broader and bolder testing needs to occur.

- ACET's charge is to advise the HHS Secretary regarding what needs to be done in order to eliminate TB. Two things need to be done: 1) foreign-born persons with LTBI need to be located, diagnosed, and treated; and 2) steps need to be taken to address the influx of people who come to the US with LTBI who need treatment. These two elements should be the highest priority for the US government. The recommendation is not going to change.
- It is clear that the community of TB programs and controllers cannot do this work alone. It is critical to engage primary care providers in the effort. The work is not only about increasing funding. Building TB program funding will not alone bring people in for diagnosis and treatment. The affected communities are not asking for this help. They may feel that TB is not a priority. The TB community needs to engage communities as well as providers and give them the tools and the desire to eliminate TB. Where possible, barriers should be removed. One of the barriers for TB programs relates to nuances of the cooperative agreement that do not allow programs to buy medications in all circumstances to treat LTBI. For instance, legal immigrants who have been in the US for less than five years and are not able to get insurance cannot receive medications from health departments.
- ACET asked that the group who is rewriting the guidelines to incorporate ACET's feedback. The guidelines should specify priority groups for testing, for instance.
- Dr. LoBue emphasized that the process is not simple, as guideline creation follows the specific GRADE process. Opinions related to TB elimination are not included in the GRADE evaluation, which is based on evidence. ACET's comments will be taken into account through the review process, however. He agreed that the large problem of the foreign-born must be addressed in order to achieve TB elimination. The companion document to the guidelines is not restricted by the GRADE process and can be more practical and instructive than the formal guidelines.
- The US military has found that initiation and completion of LTBI therapy is poor due to a combination of patients not wanting therapy and providers being unwilling to prescribe it. The military made completion of LTBI therapy compulsory.
- ACET can make recommendations and can also communicate directly with the HHS Secretary. ACET provides an annual report to the Secretary highlighting its accomplishments and the challenges that still need to be addressed. If ACET wants to send a letter to the HHS Secretary on a particular topic, the ACET chair drafts the letter and it goes through the CDC Executive Secretary up the chain of HHS.
- The response from the USPSTF regarding LTBI testing will inform ACET's strategy. If the response is positive, then ACET may articulate to the HHS Secretary that now is the time to invest more resources to make this happen. If the response is negative, then ACET can urge the Secretary to invest more resources to collect sufficient data in order to move forward. ACET might also consider the amount of resources that are needed, and where they should be directed.
- Context should be provided regardless of the USPSTF response. The availability of new tools to help move toward elimination, such as 3HP and video directly observed therapy (DOT), are the reason for this change.
- The Global Strategy to End TB was released in 2015. It represents a paradigm shift from stopping or controlling TB to ending TB. The focus is on low-prevalence countries. There is a great deal of momentum regarding elimination and it is an opportune time to build on that momentum toward elimination.

A motion was properly placed on the floor by Dr. Robert Horsburgh and seconded by Dr. Michael Lauzardo that ACET recommend to CDC and the Secretary of HHS to make available more resources in order to accomplish the goal of the elimination of TB. **The motion carried unanimously with no abstentions.**

## Workgroup Reports

### **Congregate Setting Workgroup**

**Lisa Y. Armitige, MD, PhD**

Medical Consultant

Heartland National Tuberculosis Center

University of Texas Health Center at Tyler

Chair, ACET Congregate Settings Workgroup

Dr. Armitige explained that the Congregate Workgroup was formed during the last ACET meeting, but has not yet convened. The group will meet within the next month. ACET members interested in participating on the workgroup were asked to email Dr. Armitige. The workgroup was created to focus on both homeless and corrections populations. Dr. Elson and Dr. Lauzardo volunteered to be part of the workgroup. Dr. Armitige expressed hope that Ms. Jeffries and Dr. Morris from DTBE would also join the workgroup.

### **Drug Shortages Workgroup**

**Jennifer Cochran, MPH**

Director, Division of Refugee Immigrant Health and Tuberculosis Prevention

Massachusetts Department of Public Health

Chair, ACET Drug Shortages Workgroup

Ms. Cochran said that the Drug Shortages Workgroup convened during a previous ACET meeting with her and Dr. Susan Dorman serving as co-chairs. The group briefed with CDC colleagues to determine their logical next step. Previously, the group had focused on drug supply issues and interruptions in supply. The larger issue of drugs may need to be reframed as patient access to drugs. Particularly in the context of LTBI, the issue of assuring that patients have uninterrupted supply of necessary drugs has been raised. There are different models to achieve this access. HRSA has also proposed relevant rule changes.

Ms. Donna Wegener (Executive Director, NTCA) suggested that the workgroup name could be changed to Drug Supply as opposed to Drug Shortages. There have been a number of challenges associated with the strict FDA definition of “shortage,” and the important issues incorporate supply and access. NTCA recently partnered with colleagues from the National Alliance of State and Territorial AIDS Directors (NASTAD) and NCSD regarding the issue of the Omnibus Guidance for 340B. They sent a letter on this issue with 14 state TB programs signed on. The letter focused on five key areas:

- The uniqueness of TB public health programs
- Concerns regarding the way that the patient was defined in the omnibus guidance
- Concerns about the meaning of “covered entity status,” given the arms-length relationship that programs have with providers in the field, especially if they are not providing direct treatment
- Clarification of the phrasing of “in-kind” services, particularly related to the use of federal funds to purchase items that are distributed to partners: federal DTBE funds cannot be used to purchase drugs
- The guidance should not be limited to only outpatient TB drugs; MDR-TB patients in particular need access while they are inpatients to start the regimens, which continue when they are rendered noninfectious

The most significant area is the uniqueness of public health TB programs. 340B was written for hospitals and their satellite clinics and does not fit the way that public health is organized in the US. NASTAD recommended consideration of a similar model that is a “carve-out” for AIDS Drug Assistance Programs (ADAPs). NTCA suggested that TB public health programs receive the same exemption with the removal of the restriction of income-based requirements due to the unique nature of public health. She hoped that ACET would consider making a recommendation that HRSA look at the uniqueness of public health programs and to work to remove access barriers for patients with TB infection and for 3HP.

Additional administrative support is needed for workgroups, such as in scheduling meetings and keeping minutes, to limit the constraints on the chair’s time. CDC can help with scheduling meetings. NTCA has a working group on the drug supply that can work collaboratively with an ACET chair and provide support on drug supply issues.

Dr. Dean clarified that workgroups are required to be chaired by an ACET voting member. The composition of the workgroup includes individuals interested in the topic, with DTBE participating in an advisory capacity. The workgroups usually produce a report that is presented to ACET for a vote. The report then becomes a matter of public record. Minutes can be taken of workgroup meetings and are helpful, but the minutes are not part of the public record.

Ms. Cochran said that with that added guidance and support from NTCA, the workgroup could convene with the goal of producing a report for the June ACET meeting. She proposed that the workgroup’s charge should not be drug shortages, but that the charge should be to look more broadly at drug supply and access in the particular context of LTBI. These issues are connected to the USPSTF decision. The workgroup might also review first- and second-line drugs for treatment of active TB disease.

### **Essential Components Workgroup**

**Barbara Cole, RN, MSN, PHN**

TB Controller

Riverside County (California) Department of Public Health

ACET Chair; Chair, Essential Components Workgroup

Ms. Cole is serving as chair of the Essential Components Workgroup. They are working in collaboration with NTCA. Diana Wilson is serving as co-chair. The group is reviewing the work that has already been done, with assistance from DTBE. The group is assessing gaps in the work and the input received as part of the review of the 1995 Essential Components document. There have been discussions regarding how the new document can be published.

Dr. LoBue pointed out that the *Morbidity and Mortality Weekly Report (MMWR)* is the “voice of CDC.” Items included in the *MMWR* go through an extensive clearance process. This process has been an issue with recent ACET proposals related to foreign-born guidance and to the bacille Calmette-Guérin (BCG) vaccine. Since the Essential Components document is not a formal guideline, there may be more flexibility. It could be presented to *MMWR*, but there is no guarantee that it will be published. ACET members published the BCG document in the peer-reviewed literature.

The workgroup will complete the document and make a recommendation regarding how it might be published. An ambitious goal is to have a product ready for ACET’s vote in June 2016.

### **Additional Workgroup Discussion**

- ACET expressed concern if there is a current, CDC-approved version of the Essential Components document and the potential for conflict between different versions.
- It was proposed that ACET form a workgroup on children and adolescents. A number of issues have been raised on these populations. For instance, new TB medication formulations have been released throughout the world, but there are concerns that FDA limitations will delay their introduction in the US. There are research concerns about children and adolescents. The screening of children of foreign-born parents is a notable issue. An ACET workgroup could make recommendations on research, clinical, and programmatic issues regarding TB in children and adolescents.

A motion was properly placed on the floor by Dr. Jeffrey Starke, and seconded by Dr. Robert Horsburgh, that ACET form a working group on children and adolescents. **The motion carried unanimously with no abstentions.**

The charge of the workgroup will be to consider the program, clinical, and research agendas for children and TB. It was suggested that the workgroup’s purview could incorporate repercussions associated with children having TB, such as investigations that occur at schools. Dr. Starke volunteered to serve as chair of the workgroup. Dr. Armitige and Dr. Reves volunteered to participate on the group. Any ACET members and liaison representatives interested in participating were invited to contact Dr. Starke.

With no additional comments or questions presented, Ms. Cole dismissed the group for a break at 10:11 a.m. The meeting resumed at 10:25 a.m. Dr. Dean conducted a roll call of ACET voting members, ACET *ex officio* members, and liaison representatives. A quorum was present. She reminded participants to sign in and to remain present for the day’s final roll call.

## Additional Business Items

### Status of Letter to the Secretary

Ms. Cole said that ACET received a response to ACET's letter to the HHS Secretary. The letter was a follow-up to a report that outlined ACET's issues and priorities, including:

- Shortages of anti-TB drugs, particularly second-line drugs
- Prevalence of TB in correctional and detention facilities
- TB along the US-México border
- Funding for TB elimination within DTBE, at CDC, and internationally

The follow-up letter was sent in March 2015 after a transition in HHS leadership. The letter discussed the need to focus on TB amid competing priorities, such as Ebola. It re-emphasized ACET's concerns, including intermittent drug shortages, and added the importance of maintaining a strong public health infrastructure to carry out the recommendations in the 2000 IOM TB Elimination Report. The letter asked for the opportunity to meet with the HHS Secretary or Assistant Secretary to discuss the HHS vision for TB and how ACET's priorities fit within HHS priorities and strategic direction.

The response, from the Acting Deputy Secretary of HHS on behalf of HHS Secretary Burwell, thanks ACET for raising awareness of the problems associated with TB and what needs to be done to eliminate TB. The response indicates that HHS is committed to providing resources to state and local partners to further progress toward domestic TB elimination goals and to promote the ability of partners to address emerging and re-emerging diseases. The response refers to implementation of the GHSA, how it will strengthen efforts to address TB, and how it builds capacity in countries to detect and respond to potential outbreaks. The response also indicates that HHS staff welcome the opportunity to speak with ACET further regarding how best to approach these issues.

**ACET's feedback was invited on the issues that should be highlighted in the meeting with HHS and gaps in the priorities that were already presented.** There may not be time to address all of the issues, so ACET should indicate priority points.

- ACET suggested adding the issue of LTBI to the list. WHO and the US government are now considering ending TB, which requires addressing the reservoir of infection. There is a need for strategies and coordination of resources within the federal government. HHS can help coordinate the response. WHO has made recommendations for low-burden countries in this area, and the US needs the Secretary's leadership to engage.
- Further, the meeting should emphasize that TB cannot be eliminated without addressing LTBI. Resources should be directed at increasing the number of people brought treated for LTBI in order to reduce prevalence. This issue should be a top priority.
- Prior to the meeting, ACET should understand who the government agency partners might be and what the costs might be. It is also important to understand the USPSTF response before the meeting.

- ACET should endeavor to convene after the USPSTF response is released to discuss what the “ask” should be at the HHS meeting. The “ask” should be very specific.
- CDC funded community-based organizations (CBOs) to engage in HIV and in hepatitis C in the Asian American community. Involvement from these groups is facilitated by this support. CBOs advocated for attention and funding for hepatitis C and for hepatitis B. They were motivated and articulate in their advocacy. ACET can share success stories of this support in other disease issues. There are examples of these successes within NCHHSTP. TB and public health are not just a federal issue. ACET is not asking the HHS Secretary to do it all. Federal leadership will help states and cities remain engaged in the process.
- ACET’s letter to the Secretary summarized a year of work. The world has moved forward since the letter was written. The elevation of LTBI has become important. The meeting is an opportunity to discuss the present and future of TB, not only its past. The BARDA question could also be considered. ACET should revisit that issue before the HHS meeting.
- Questions about TB in detention and correctional facilities could be highlighted.
- The meeting should not focus on the problems, but on the potential solutions to them. For instance, FDA regulations could be change to ameliorate problems with the drug supply. If a problem does not have a proposed solution, then it should not be on the agenda for the meeting.
- Maintaining the public health infrastructure remains important. The infrastructure could be expanded to include issues such as data analysis capacity for programs, especially in implementation science and in using data to drive decision-making in programs. The Essential Components work also ties into this idea.
- The President has become interested in resistant organisms, as evidenced by the CARB initiative and others like it. Prevention of resistance in TB incorporates preventing transmission, completing therapy, and initiating preventive therapy. This component of TB work might engage people.

Ms. Cole summarized that the timing of the meeting will be important, particularly regarding the USPSTF recommendations. ACET agreed that the meeting should not take place prior to release of those recommendations. ACET agreed that the items in the letter are still relevant, but the discussion should integrate addressing LTBI in order to move toward TB elimination. Before the meeting, ACET will define its “ask” specifically and succinctly.

### **USPSTF Update**

As soon as CDC is notified that a draft of the USPSTF recommendations is available for public comment, it will be distributed to ACET. It is possible that the public comment period for the recommendations will be open when ACET meets in 2016.

Ms. Cole reminded the group that ACET only conducts business in formal meetings or in workgroup meetings. Depending on the timing of the release of the recommendations, ACET may not have an opportunity to generate collective comments. Individuals and organizations can respond on their own. The grading is not known, but USPSTF accepted many of ACET’s comments on the draft document. An A or B grade from USPSTF will allow for coverage for LTBI with no copay.



### **Board of Scientific Counselors (BSC) Meeting**

Ms. Cole reported that the OID BSC met recently. The meeting included a focused discussion of different aspects of *Legionella*. There may be lessons learned for TB from that experience. The meeting also included discussion of the Food Safety Modernization Act. A Surveillance Workgroup of the BSC has made a number of recommendations and provided an annual report to the HHS Secretary. The Laboratory Workgroup of the BSC is addressing important areas such as culture-independent diagnostic tests, point-of-care testing, AMD, the use of forms of Nucleic Acid Amplification (NAA) to consider infectiousness of patients and isolation, and WGS.

### **Future Dates of ACET Meetings**

Ms. Cole presented the following proposed ACET meeting dates for 2016:

- ☐ March 2, 2016 (Webinar)
- ☐ June 1, 2016 (Webinar)
- ☐ December 6-7, 2016 (in person)

### **ACET's input was requested regarding how to make the webinars more effective.**

- Some participants cannot connect via Live Meeting because of security requirements at their agencies, so participation can be challenging. It can also be difficult to identify who is speaking, and the sound occasionally goes in and out. The audio-visual specialist for CDC indicated that Adobe Connect is anticipated to be rolled out for CDC usage in 2016. Live Meeting will no longer be used, and Adobe Connect will be the preferred platform for CDC webinars in 2016.
- ACET emphasized that in-person meetings are more effective for conducting business.
- The webinars are organized for maximum efficiency, as limited business is carried out in a short period of time. They focus not on presentations, but on important information that will carry ACET to its next meeting. It is not possible to have more in-person meetings. The new platform for the webinars is likely to make them more effective, but there may be other ways to enhance the meeting.
- There was discussion regarding the possibility of scheduling another ACET webinar in the fall of 2016 to sustain momentum. An additional meeting could be a budget concern. ACET members will be polled regarding possible meeting dates for a fall webinar.

### **Potential Agenda Topics for the Next Meeting**

- It was proposed that the agenda of the next ACET meeting should focus entirely on the upcoming meeting with the HHS Assistant Secretary, especially on the results of the USPSTF recommendations and what ACET's "ask" of HHS should be, as well as economic aspects of these issues.
- The availability of data from NEEMA modeling studies on this issue will be important in informing ACET's discussions. Information regarding modeling cost-effectiveness of targeted LTBI testing will be useful regardless of the status of the USPSTF response.
- There was consensus among ACET that the March 2016 webinar should focus primarily on the USPSTF response, provided that it will be available. If the response is not available, then the ACET meeting can focus on the approach to the upcoming meeting with a representative from HHS.

Ms. Cole noted that a past ACET agenda item request was for a status report on potential funding of a new join NTCA/CDC targeted prevention initiative. The initiative was not put forward in the budget.

**ACET's input was requested regarding next steps pertaining to BARDA.**

- Initially, ACET had discussed BARDA as a potential source of funding to purchase medication or for stockpiling. From the previous day's presentation, it does not seem that BARDA is an option in that area. Their assistance in stewardship is encouraging, however, as well as their expertise in managing supply. There could be opportunities to partner with BARDA in dual-purpose areas with relatively minimal effort.
- The ACET Drug Supply Workgroup could consider opportunities to interface with BARDA regarding drug supply.
- There was a discussion regarding a mechanism to share data that might help inform the discussions around LTBI, specifically prioritizing contacts. In moving to the broader message of widespread testing, health departments still need priorities and the importance of contacts should not be forgotten. Any such information should be sent to Ms. Margie Scott-Cseh, and it will be approved and distributed to ACET.
- ACET discussed marketing, an important aspect of health. The TB community has a difficult message to market, because the approaches to testing are discriminatory, in a non-pejorative sense, as a group of individuals should be targeted for testing. It will be difficult to make this approach palatable. Marketing expertise is likely to be required. The testing should be marketed as a service, similar to hepatitis B testing in certain communities.

**Public Comment**

Ms. Cole said that the scheduled public comment would come from a person who will help make ACET aware of the personal impact that TB can have on individuals and their families, and of the action that can be taken to address the issues. She noted that a film crew was present to film the speaker.

**Donna Wegener**

Executive Director, National Association of TB Controllers

Ms. Wegener introduced Ms. Carrie Fritchey, one of NTCA's 2015 TB Ambassadors. The TB community envies colleagues in HIV for their funding, messaging, marketing, and empowering patients to speak out for what they need. There has not been a parallel movement in TB. It is apparent that TB needs partners that extend beyond current audiences. In partnership with Stop TB USA and Results, and a collection of other organizations, NTCA introduced the first Patient Communications Workshop. The workshop has led to a phenomenal movement to raise awareness and foster community among TB survivors. With Ms. Fritchey's leadership, TB has a strong advocacy support community.

## **Carrie Fritchey TB Ambassadors**

Ms. Carrie Fritchey thanked ACET for the opportunity to speak and share the vision for a TB Ambassador program. She hoped to partner with ACET to eliminate TB in the US and globally. The TB Ambassadors are determined to make TB a disease that people are aware of.

*"... We must give a voice to those with TB who are currently voiceless." - Dr. Eric Goosby*

The only way to raise awareness about TB is to share the stories of people who have been through it and to give people a reason to care about it. Ms. Fritchey did not think that TB existed anymore when her daughter was diagnosed with it. They encountered many misconceptions about the disease.

Ms. Fritchey's daughter battled TB for a year. It took five months for her to be diagnosed. As the child continued to spike high fevers, pediatricians worked to determine what was wrong with her: ear infection, sinus infection, respiratory syncytial virus (RSV), pneumonia. She had rashes, which are not a pediatric symptom of TB. She was treated with antibiotics and other methodologies, but the fevers returned. A 30-day follow-up chest x-ray indicated the possibility of chronic lung disease. The pediatrician suggested testing for TB to rule it out. The child's reaction to the TST was fast and obvious. Ms. Fritchey was somewhat encouraged, thinking "we can treat this, this is treatable!" The family did not know how long the treatment was or what it entailed. Even though the child was small, could not produce a sputum sample for a culture, and was not contagious, security measures at the hospital included covering her in a sheet. The communication with providers was nonexistent, putting the family on a rollercoaster of emotions.

Because it was not possible to obtain a culture, the first two months of the treatment regimen were uncertain, as it was not clear whether the medication was working or whether Ms. Fritchey's daughter might have MDR-TB or XDR-TB. The family received strong support from public health, but they were advised not to disclose the TB diagnosis and treatment to anyone. The public does not know what TB is and is frightened of it. Even close family and friends were somewhat hesitant to be around the child. She received DOT through the public health system two to three times per week. The therapy was not ideal, but it was effective. The recovery was as good as could be expected, and her daughter is now four years old. It is not acceptable that children continue to die of TB. TB can be cured.

Ms. Fritchey believes that everything happens for a reason, and she reached out to participate in World TB Day activities. She spoke on behalf of her daughter at the Four Corners Conference in Santa Fe, New Mexico where she met Ms. Wegener. They discussed building a survivor group that could serve as ambassadors and voices for the cause of TB, reducing stigma, and building awareness about TB. Ms. Fritchey's company created a competition program in which 100 hours of paid time off were awarded to employees to partner with a nonprofit. Ms. Fritchey was one of four employees selected for the program and to have a documentary made about their work. The documentary can educate patients and encourage them to participate in the ambassador program.

The first survivor training was held in June 2015 with seven participants, six of whom have remained in the program and are committed to raising awareness. Their stories are being crafted in written form to serve as a resource. The next training will take place at the February 2016 NTCA conference in Denver, Colorado. Twenty new applications to participate in the training

have been received so far. Funding is needed to support bringing these participants to Denver. Several outlets have helped share information about the program and the Fritchey family story. The group has a “We Are TB” Facebook page so that they can communicate and keep each other motivated.






The TB Ambassadors mission is to create a team of survivors who will serve as TB Ambassadors willing to raise awareness about tuberculosis with three fundamental goals:

- Provide an informative and supportive community for patients and survivors.
  - New patients need help and support. For example, Ms. Fritchey was called to schedule an HIV test for her daughter. The testing is routine, but she was unaware of the correlations and risk factors with HIV and TB. A survivor group can help patients navigate these situations.
- Share personal stories to drive change at a local, state and/or national level.
  - One of the TB Ambassadors recently shared her story on MDR-TB with Congress. They communicate with policymakers regarding support for the National Plan to End TB.
- Provide the media a TB patient perspective to educate and reduce the stigma of TB.
  - Ambassadors can play an important role with the media, which tend to play up the fear factor. More ambassadors are needed to build momentum to sway public opinion and raise public knowledge.

Ms. Fritchey shared the following details about each of the ambassadors:

## THE AMBASSADORS

Each survivor in the inaugural TB Survivor Training is dedicated to fulfill this mission and provide unique perspective and experiences with the journey through TB.

	Shaka Brown   Professional Salsa Dancer   Disseminated TB
	Zee Pinkerton   Active TB in High School
	Laura Guterrez   Elementary Teacher Bombarded by Media
	Tenzin Kenhrap   Lost Hearing Due to Treatment
	Scarlett Fritschy   Pediatric TB
	Nora Rodriguez   MDR TB

Of the group of six, half are foreign-born, and the other half became infected after traveling outside the US. As travel becomes more and more popular, TB risk will increase.

Ms. Fritchey asked ACET to:

1. Utilize survivors in elimination plans. Survivors can help share messages and “put a face” to this confusing disease. Survivors can also help at the primary care level, where there are gaps in knowledge regarding how to address TB.
2. “Let us be the voice to the cause.” Partner with those who have lived through the treatment to work on the local, state, national, and global levels; advise CDC to do the same.

Ms. Fritchey emphasized that survivors want to be a part of the elimination effort. She asked that ACET consider including a TB survivor on the council to provide a different perspective. A TB survivor can add value to the effort.

ACET discussed Ms. Fritchey’s presentation.

- The TB Ambassadors group does not yet have an official structure. Their next step is to build and structure the organization. The training is a joint effort of NTCA, Stop TB USA, and Results. A number of other organizations are providing support from a facilitation aspect. The energy of the group is coming from within the population, and the organizations serve to support them. Ms. Fritchey’s passion as a catalyst, and her company’s commitment of volunteer hours, are driving this effort and seeing it grow.
- ACET hoped that CDC would consider including a TB survivor representative on ACET. Ms. Fritchey was invited to participate in the ACET Children and Adolescents Workgroup. ACET and DTBE seek to consider issues of diversity and to be inclusive of the groups that are impacted by TB. Representation from these groups is needed. Healthcare providers have a notion of what the provision of healthcare entails, but firsthand experience as a patient in the system brings different perceptions of what is, and what should be. Stop TB USA and NTCA have worked to create a community and patient forum to amass enough TB ambassadors. Each has a different story and different concerns. TB diagnoses are difficult, even in the best circumstances, and people need to be supported when the diagnoses are made.
- Prospective patients can speak to a current TB Ambassador to learn more about the group. There is still stigma associated with TB so that people are reluctant to share their stories, but as the ambassador movement grows with people who are not ashamed to talk, others will be encouraged to come forward and share their stories.
- There was discussion regarding how the TB Ambassador group might protect itself against Internet predators or unscrupulous people. The group is careful in how information is disseminated. Through partner organizations, the group reaches directly to public health. Applicants to participate in the training are nominated by someone in public health. The process also includes an interview and review.
- It is critical for public health to not to continue stigmatization. It is time to catch up with where patients want us to be in talking about TB. Healthcare providers may be conflicted by the importance of maintaining confidentiality and minimizing stigmatization. Public health should not tell the TB patients’ stories for them. The patients and survivors must be willing to tell the stories. Those stories will move policymakers and other funders to support TB elimination. A message from the affected community is different from a message from public health.

A motion was properly placed on the floor by Dr. Michael Lauzardo and seconded by Dr. Ana Alvarez that ACET recommend to CDC to work with the HHS Secretary's office regarding the possibility of including a survivor / TB patient advocate to serve on ACET. The motion was amended to indicate that if it is not allowable to have such a representative on ACET under its current charter, then ACET requests an amendment of the charter to allow for this representation. **The motion carried unanimously with no abstentions.**

Dr. Dean reviewed ACET's charter, which includes specific language regarding ACET members being "authorities" in certain fields. She will talk with CDC's Office of General Counsel to learn whether a person who is infected with TB or affected TB can be included as a voting member of ACET. There are two other non-voting representative categories of ACET members: federal agency representatives, and organizations that either treat TB patients or focus on TB. CDC puts forth the names and credentials of potential ACET members to the HHS Secretary, who approves the members. There have been instances in which the Secretary has not approved nominees to ACET. The charter for the Advisory Committee for HIV, STD, and Hepatitis requires that the group include members who are infected with HIV on their voting membership.



Ms. Cole listed follow-up items for ACET:

- The Agenda Workgroup will meet and consider input from ACET's discussion in setting the next ACET meeting agenda.
- Dr. Armitige will convene the Congregate Setting Workgroup.
- Ms. Cochran will convene the Drug Supply Workgroup.
- Ms. Cole will convene the Essential Components Workgroup.
- The March ACET meeting will focus on the upcoming meeting with HHS.
- ACET will continue to monitor the LTBI reporting system.
- ACET will monitor the USPSTF recommendations.
- ACET will consider leveraging existing partners to move into operational research.

Ms. Cole thanked the meeting participants for their input and engagement.

Dr. Dean conducted roll call and established that a quorum of ACET voting members, *ex officio* members, and liaison representatives was present.

A motion was properly placed on the floor by Dr. James Sunstrum, and seconded by Dr. Jeffrey Starke, to adjourn the December 2015 ACET meeting. **The motion carried unanimously with no abstentions.**

The meeting stood adjourned at 11:57 a.m.

### **Certification**

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the December 15-16, 2015, meeting of the Advisory Council for the Elimination of Tuberculosis, CDC, are accurate and complete.

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Date

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Barbara Cole, RN, MSN, PHN  
Chair, Advisory Council for the Elimination of  
Tuberculosis, CDC





## **Attachment 1: Participant Directory**

### **ACET Members Present**

Ms. Barbara Cole (Chair)  
Dr. Ana Alvarez  
Dr. Lisa Armitige  
Ms. Jennifer Cochran  
Dr. C. Robert Horsburgh

Dr. Eric Houpt  
Dr. Michael Lauzardo  
Dr. Jeffrey Starke  
Dr. James Sunstrum  
Dr. David Warshauer

### **ACET ex officio Members Present**

William Baine, MD, FACP  
Agency for Healthcare Research and  
Quality

Diana Elson, DrPH, MA, CDR USPHS  
US Immigration and Customs Enforcement

Michael Bartholomew, MD, FAAP  
Indian Health Service

Caroline Freeman  
US Department of Labor, Occupational  
Safety and Health Administration

Amy Bloom, MD  
US Agency for International Development

J. Nadine Gracia, MD, MSCE  
Office of Minority Health, US Department of  
Health and Human Services

Sarah Bur, RN, MPH  
Federal Bureau of Prisons

Mamodikoe Makhene, MD, MPH  
National Institute of Allergy and Infectious  
Diseases  
National Institutes of Health

Anthony Campbell, RPH, DO  
Substance Abuse and Mental Health  
Services Administration

James Mancuso, MD, DrPh  
(Alternate for Naomi Aronson)  
US Department of Defense

Edward Chin  
US Marshals Service

Stephen Martin  
National Institute for Occupational Safety  
and Health  
Centers for Disease Control and Prevention

Rupali Doshi, MD, MS  
HIV/AIDS Bureau, Health Resources and  
Services Administration

Karen Elkins, PhD  
US Food and Drug Administration

Gary Roselle, MD  
US Department of Veterans Affairs

### **ACET ex officio Members Absent**

Bruce San Filippo, MD  
US-México Border Health Commission

### **ACET Liaison Representatives Present**

Shama Desai Ahuja, PhD, MPH  
Council of State and Territorial  
Epidemiologists

Robert Belknap, MD  
National TB Controllers Association

Robert Benjamin, MD, MPH  
National Association of County and City  
Health Officials

Jay C. Butler, MD, CPE, FAAP, FACP,  
FIDSA  
Association of State and Territorial Health  
Officials

Mayleen Ekiek, MD

### **ACET Liaison Members Absent**

David Bryden  
RESULTS

Fran Du Melle, MS  
American Thoracic Society

Kenyon Farrow  
Treatment Action Group

Eddie Hedrick, BS, MT (ASCP), CIC  
Association for Professionals in Infection  
Control and Epidemiology

Ilse Levin, DO, MPH & TM  
American Medical Association

John Lozier  
National Coalition for the Homeless

### **ACET Designated Federal Officer**

Hazel Dean, ScD, MPH  
Deputy Director, NCHHSTP

### **CDC Representatives**

Ms. Leeanna Allen  
Dr. Stuart Berman  
Dr. Terence Chorbá  
Ms. Ann Cronin  
Ms. Molly Dowling

Pacific Island Health Officers Association

Howard Njoo, MD, MHSc, FRCPC  
Public Health Agency of Canada

Ameé Patrawalla, MD, MPH, FCCP  
American College of Chest Physicians

Susan Rappaport, MPH  
American Lung Association

Susan Ray, MD  
Infectious Disease Society of America

Randal Reves, MD  
International Union Against TB and Lung  
Disease

Jennifer Rakeman, PhD  
Association of Public Health Laboratories

Gudelia Rangel, PhD  
México Section, US-México Border Health  
Commission

Michael Tapper, MD  
Society for Healthcare Epidemiology of  
America

Lornel Tompkins, MD  
National Medical Association

Tara Wildes  
Jails Division, National Commission on  
Correctional Health

Dr. Wayne Duffus  
Ms. Maria Galvis  
Ms. Macarena García  
Dr. Shannon Hader  
Dr. Christine Ho

Ms. Carla Jeffries  
Mr. Gary Johnson  
Mr. Steve Kammerer  
Ms. Kathryn Koski  
Ms. Lauren Lambert  
Dr. Philip LoBue  
Ms. Suzanna Marks  
Dr. Jonathan Mermin  
Mr. Mark Miner  
Mr. Roque Miramontes  
Dr. Sapna Morris  
Ms. Lilia Manangan  
Dr. Tom Navin  
Mr. Samuel Parks  
Dr. John Parmer

**Members of the Public**

Kanchana Amaratunga MD, MPH  
Public Health Agency of Canada

Kendra Cox, MA  
Cambridge Communications

Jennifer Flood, MD, MPH  
California Department of Public Health

Carrie Fritchey  
TB Ambassadors  
National Association of TB Controllers

Nicole Lurie, MD, MSPH  
Assistant Secretary for Preparedness  
and Response  
US Department of Health and Human  
Services

Ms. Rose Punnoose  
Mr. John Ridderhof  
Mr. Jorge L. Salinas  
Ms. Margie Scott-Cseh  
Ms. Sarah Segerlind  
Ms. Maria Fraire Sessions  
Dr. Benjamin Silk  
Mr. Brian Sizemore  
Mr. Duane Stone  
Ms. Dana Tumblin  
Dr. Thara Venkatappa  
Dr. Andrew Vernon  
Dr. Wanda Walton  
Mr. Matt Whipple  
Dr. Carla Winston

Mike Sarge  
Stop TB USA

BJ Schulz  
National TB Controllers Association

Ben Brue  
National TB Controllers Association

Judith Thigpen, MPH  
California TB Controllers Association

Lauren Underwood, RN  
Assistant Secretary for Preparedness and  
Response  
US Department of Health and Human  
Services

Donna Wegener  
National TB Controllers Association



## **Attachment 2: Glossary of Acronyms**

<b>Acronym</b>	<b>Expansion</b>
AAFP	American Association of Family Practitioners
AAP	American Academy of Pediatrics
ACA	(Patient Protection and) Affordable Care Act
ACET	Advisory Council for the Elimination of Tuberculosis
ACTG	AIDS Clinical Trials Group
ADAP	AIDS Drug Assistance Program
AHRQ	Agency for Healthcare Research and Quality
AMD	Advanced Molecular Detection
AMR	Antimicrobial Resistance
APHL	Association of Public Health Laboratories
ART	Antiretroviral Therapy
ASPR	Assistant Secretary for Preparedness and Response
ATS	American Thoracic Society
BARDA	Biomedical Advanced Research and Development Authority
BCG	bacille Calmette-Guérin (vaccination)
BSC	Board of Scientific Counselors
CARB	(National Strategy for) Combatting Antibiotic-Resistant Bacteria
CBO	Community-Based Organization
CDC	Centers for Disease Control and Prevention
CGH	Center for Global Health
CI	Confidence Interval
CIADM	Center for Innovation and Advanced Development in Manufacturing
CMO	Committee Management Office
CoC	Continuum of Care
CSTE	Council of State and Territorial Epidemiologists
DASH	Division of Adolescent and School Health
DC	District of Columbia
DFO	Designated Federal Officer
DGMQ	Division of Global Migration and Quarantine
DHAP	Division of HIV/AIDS Prevention
DHS	(United States) Department of Homeland Security
DIS	Disease Intervention Specialists
DoD	(United States) Department of Defense
DOT	directly observed therapy
DST	Drug Susceptibility Testing (Reference Center)
DSTD	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
DVH	Division of Viral Hepatitis
EDN	Electronic Disease Notification

Acronym	Expansion
EHR	Electronic Health Record
EIS	Epidemic Intelligence Service
ELR	Electronic Laboratory Report
FACA	Federal Advisory Committee Act
FDA	(United States) Food and Drug Administration
FOA	Funding Opportunity Announcement
FQHC	Federally Qualified Health Center
FY	Fiscal Year
GHS	Global Health Security
GHSA	Global Health Security Agenda
GIS	Global Information Systems
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HCV	Hepatitis C Virus
HHS	(United States) Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HMIS	Homeless Management Information System
HMO	Health Maintenance Organization
HRSA	Health Resources and Services Administration
HUD	(United States Department of) Housing and Urban Development
ICE	(United States) Immigration and Customs Enforcement
IDSA	Infectious Disease Society of America
IDU	Intravenous Drug User
IGRA	Interferon-Gamma Release Assay
IHR	International Health Regulations
IHS	Indian Health Service
IOM	Institute of Medicine
ISO	International Organization for Standardization
IT	Information Technology
LGB	Lesbian, Gay, and Bisexual
LTBI	Latent Tuberculosis Infection
MDR-TB	Multidrug-Resistant Tuberculosis
MEDSIS	Medical Electronic Disease Surveillance Intelligence System
MERS	Middle East Respiratory Syndrome
mm	millimeter
MMWR	Morbidity and Mortality Weekly Report
MOH	Ministry of Health
MSM	Men who have sex with men
NAA	Nucleic Acid Amplification
NACCHO	National Association of City and County Health Officials
NAP	National Action Plan
NASTAD	National Alliance of State and Territorial AIDS Directors
NCCHC	National Commission on Correctional Healthcare
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NCSD	National Coalition of STD Directors
NDMS	National Disaster Medical System
NEEMA	NCHHSTP Epidemiologic and Economic Modeling Agreement
NHANES	National Health and Nutrition Examination Survey

Acronym	Expansion
NHCHC	National Health Care for the Homeless Council
NHSS	National Health Security Strategy
NIH	National Institutes of Health
NTCA	National Tuberculosis Controllers Association
NTGSN	National TB Genotyping and Surveillance Network
OID	Office of Infectious Diseases
PEPFAR	President's Emergency Plan for AIDS Relief
PHAB	Public Health Accreditation Board
PHAC	Public Health Agency of Canada
PHEMCE	Public Health Emergency Medical Countermeasure Enterprise
PPD	Purified Protein Derivative
PPE	Personal Protective Equipment
PrEP	Pre-Exposure Prophylaxis
QFT	QuantiFERON-TB test
RFP	Request for Proposals
RSV	Respiratory Syncytial Virus
RTMCC	Regional Training and Medical Consultation Center
RVCT	Report of Verified Case of Tuberculosis
SAMHSA	Substance Abuse and Mental Health Services Administration
SDOH	Social Determinants of Health
SME	Subject Matter Expert
SNS	Strategic National Stockpile
SNTC	Southeastern National Tuberculosis Center
SOC	Secretary's Operations Center
STD	Sexually Transmitted Disease
TB	Tuberculosis
TBESC	Tuberculosis Epidemiologic Studies Consortium
TBTC	Tuberculosis Trials Consortium
TST	Tuberculin Skin Test
UNICEF	United Nations Children's Fund
US	United States
USDA	United States Department of Agriculture
USICH	United States Interagency Council on Homelessness
USPSTF	United States Preventive Services Task Force
VA	(United States Department of) Veterans Affairs
VMI	Vendor-Managed Inventory
WGS	Whole Genome Sequencing
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant Tuberculosis
XPRES	Xpert Package Rollout Evaluation Study